March 23, 2018 P.M. (AMENDED)

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 23, 2018 12:54 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S AMENDED TRANSCRIPT OF PROCEEDINGS
(Amended to correct date on cover page)

JURY TRIAL - DAY 7 P.M.

(Pages 1450 through 1594)

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I N D E X

TESTIMONY

E X H I B I T S

E X H I B I T S (Continued)

Number		Ident	Rec'd
5169	Apr. 25, 2003 Recovery Retrievable Abbreviated 510(k) (K031328)	1496	1497
5177	Nov. 27, 2002 FDA Clearance Letter re Recovery Permanent (K022236) (Substantial Equivalence)	1495	1496
5189	July 10, 2002 IMPRA Recovery Permanent Special 510(k) (K022236)	1493	1495
5193	Feb. 28, 2005 Letter BPV to FDA re FDA AI re Recovery Retrievable (K031328)	1531	1532
5195	Nov. 30, 2004 Letter FDA to BPV re Recovery IFU and DDL	1505	1505
5196	Oct. 5, 2004 Letter BPV to FDA re Recovery IFU and DDL	1503	1504
5197	July 25, 2003 FDA Clearance Letter re Recovery Retrievable (K031328) (Substantial Equivalence)	1498	1503
5238	Slides from Bariatric Surgeons Panel Meeting on Feb. 12, 2005	1515	1516
5239	Jan. 21, 2005 Conference FDA and BPV re DDL and Recovery Retrievable (K031328)	1524	
5247	May 11, 2005 BPV began distributing DCL	1507	1508
5323	Aug. 8, 2005 FDA Grants BPV Conditional Approval for G2 Everest Study (G050134)	1543	1543
5324	July 8, 2005 BPV's original IDE submission re G2 Everest Study (G050134)	1542	1543
5325	Oct. 3, 2005 Letter BPV to FDA re G2 Everest Study (G051034) and Conditional Approval	1543	1544
5329			1529

E X H I B I T S (Continued)

Number		Ident	Rec'd
5333	Feb. 2, 2007 Letter BPV to FDA re G2 Everest Study (G051304) Annual Progress Report	1544	1545
5344	July 28, 2005 Letter FDA to BPV re AI re Modified Recovery (K050558)	1537	1539
5349	Mar. 2, 2005 BPV's Modified Recovery Filter Special 510(k) (K050558)	1533	1533
5350	June 3, 2005 Letter BPV to FDA re Modified Recovery conversion Traditional 510(k) (K050558)	1536	1537
5354	Sept. 19, 2005 BPV's G2 Filter - Jugular Subclavian Delivery Kit Special 510(k) (K052578)	1540	1541
5361	Sept. 25, 2006 BPV's G2 Filter - Femoral Delivery Kit Special 510(k) (K062887)	1541	1542
5534	Picture of Clot from Feb. 2004 RNF Migration	1501	1502
5539	G2 Caudual Migration Failure Investigation Report Aug. 4, 2005 G2 Filter Caudal Migration Failure Investigation Report (FIR-06-01-01) G2 Caudual Migration Failure Investigation Report	1555	1556
5879	April 11, 2006 Letter to FDA re Caudal Migration	1553	1554
5880	March 23, 2006 Letter to FDA re G2 Caudal Migration	1554	1555
5881	April 11, 2006 Letter to FDA re Caudal Migration	1550	1551
5905	Jan. 22, 2005 Email to FDA	1533	1534
6046	August 28, 2006 EVEREST Medical Monitor Adjudication Meeting Minutes	1575	1576

E X H I B I T S (Continued)

Number		Ident	Rec'd
7753	2014 Draft FDA Guidance re Benefit-Risk Factors When Determining Substantial Equivalence in Premarket Notifications 510k with Different Technological Characteristics	1479	1459
7758	2014 FDA Guidance re 510k Evaluating Substantial Equivalence in Premarket Notifications	1476	1459
7795	Screenshot from FDA, MAUDE - Manufacturer and User Facility Device Experience, available online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm	1485	1459

MISCELLANEOUS NOTATIONS

Item	Page
Proceedings outside the presence of the jury	1457

RECESSES

	Page	Line
(Recess at 2:36; resumed at 2:46.)	1522	9

P R O C E E D I N G S

(Court was called to order by the courtroom deputy.)

(Proceedings begin at 12:54.)

(The following proceedings occurred in open court outside the presence of the jury.) 12:54:41

THE COURT: Thank you. Please be seated.

Counsel, give me just a minute to just check something in my notes.

All right. Counsel, I've had a chance to read the section in the Weinstein's treatise on 803(8). We've looked at 12:56:03 some related case law as well and we've looked at those exhibits. My conclusion is that the three guidance documents which are, according to folders I have been given, Exhibits 5126, 7753, and 7758, are documents that set forth activities of the FDA within the meaning of Rule 830(8)(A)(i). 12:56:36

And just to put on the record my reasons. If I look, for example, at Exhibit 7753 and turn to page three, there's a discussion that talks about what FDA must find to approve, what it must determine, what it will review, what it must evaluate. Again, what it will determine, what it will consider, clearly a 12:57:05 description of the FDA's activities for purposes of reviewing the submissions covered by that guidance document.

Similarly, in Exhibit 7758 there's even a flowchart outlining FDA activities and how they make decisions and what has to be submitted at various places and similar information 12:57:29

in 5126. 12:57:34

So my conclusion is that these documents fall within 830(8)(A)(i) as activities of a Government agency and I'm going to overrule the hearsay objection for that rule -- or for that reason. 12:57:52

With respect to the website screen shot which is docket 7795, it, too, describes FDA activities. It begins by saying each year FDA receives several hundred thousand medical device reports and it goes on to describe what FDA does with that and what information it releases and what information it seeks to include in reports. 12:58:13

So I think this document as well reflects the activities of the FDA within 803(8)(A)(i) and is admissible.

I also note that at least four cases cited in Weinstein held that federal government websites are admissible under 803(8), so I'm going to overrule the hearsay objection on that document as well. 12:58:32

And I think those were all of the exhibits that we were given and I'll give them back to you, Mr. North.

Traci, why don't we see if the jury is ready? 12:59:05

Read me those exhibit numbers again, Mr. North, so I can tell the jury they have been admitted.

MR. NORTH: 7795, 5126, 7753 and 7758.

THE COURT: Okay.

Let's go ahead and have the witness come back in. 01:00:03

(Jury enters at 1:00.) 01:00:07

THE COURT: Thank you. Please be seated. Dr. Tillman, you can come back up to the witness stand.

All right. Ladies and gentlemen, before the noon break there were four exhibits offered in evidence that I took under advisement. I am now going to admit those exhibits. They are Exhibits 5126, 7753, 7758, and 7795. They are the three FDA guidance documents and the screen shot from the FDA. 01:00:48

Mr. Johnson, you may continue.

(Exhibit Numbers 5126, 7753, 7758, 7795 were admitted into evidence.) 01:01:14

MR. JOHNSON: Thank you, Your Honor.

(DONNA TILLMAN, PH.D., a witness herein, was previously duly sworn or affirmed.)

CROSS - EXAMINATION (Continued) 01:01:21

BY MR. JOHNSON:

Q. Can we start with Exhibit 2052. Ma'am, before we get to page 18 of that exhibit, we talked earlier about the EVEREST study and it being a six-month study. Do you remember that?

A. Yes. 01:01:35

Q. And what we don't know through EVEREST is whether any trends continued beyond six months. Agreed?

A. Whether any trends in what?

Q. The complications that were exhibited in that study?

A. That's right. That's correct. We only know the data as 01:01:52

of the end of the EVEREST study, that is correct. 01:01:56
Q. All right. And those are safety trends that we're talking about and safety concerns. That is when a filter migrates and penetrates the vena cava. Agreed?
A. Yes. Those are certainly potential adverse events. 01:02:08
Q. And you can understand how it might be important to the end user, the patient, the Ms. Bookers of the world, to know whether those trends continued. Agreed?
A. I would agree that it's important to understand the long-term performance of a device, yes. 01:02:30
Q. And a company like Bard doesn't need the FDA to tell it to continue a study or to do a long-term safety study. Agreed?
A. I would agree that the company doesn't need FDA to tell it.
Q. All right. And if it's the right thing to do, you should do it. Agreed? 01:02:48
A. I would agree that if there are important scientific questions that need to be answered, then a study should be done, yes.
Q. All right. 01:03:00
MR. JOHNSON: And, Greg, let's publish page 18 of Exhibit 2052.
BY MR. JOHNSON:
Q. I would like you to assume that this is a Bard document.
MR. JOHNSON: May I publish this, Your Honor? I 01:03:14

think we had it up before we broke for lunch. 01:03:16

THE COURT: You may.

BY MR. JOHNSON:

Q. I would like you to assume that this is a Bard document. Do you know what a Type A fracture is and what a Type B fracture is? 01:03:27

A. Not as I'm sitting here today, no.

Q. Just assume for purposes of what I'm talking to you about that Type A fractures are a much more clinically significant fracture compared to Type B; okay? 01:03:41

A. Okay. I can assume that.

Q. I would like you to assume that this trending analysis was done after the EVEREST study; okay?

A. Okay.

Q. And what this comparative table shows us is that the Type A, the worst fracture, is attributed to the G2 compared to the Recovery filter. Do you see that? 01:03:54

A. Can you please explain to me what this is a percentage of? So a percentage means you have one number divided by another. So what is the percentage we're showing here? 01:04:15

Q. We do see that 52 percent for G2 is higher than the 46 percent for the Recovery. You agree with that?

A. Well, the number 54 is bigger than 46 but I don't understand what these percentages are. Can you explain that?

Q. Well, you know what, I wish I could testify, but I don't 01:04:30

think Judge Campbell will let me. This was a document that was not given to you; correct? 01:04:33

A. I actually did see this document in a deposition.

Q. Now let's go farther down to caudal migration and we know what caudal migration is and it indicates that with the G2, the caudal migration is 14 percent and for the Recovery filter, it's three percent. Do you see that? 01:04:50

A. I see that there's a 14 percent and a three percent but, once again, I'm not sure, percent of what?

Q. Well, let's go to the comments section that is contained in this Bard document. What did Bard say about that? 01:05:08

A. In this column it says that G2 more caudal than RNF.

Q. Okay. Indicating to you that there is more caudal migration with the G2 compared to the Recovery filter?

A. I can't conclude that because I don't know what the basis of these numbers is. 01:05:31

Q. Okay. But looking at those, looking at the comments, that's what it appears to indicate. Agreed?

A. I can't comment on these numbers without knowing where they came from. 01:05:44

Q. Okay. That's all right.

Let's go down to tilt. Do you see where we have a higher number for tilt associated with the G2 Filter compared to the Recovery filter?

A. I see where it says that on the slide, yes. 01:06:02

Q. And the tilt percentage for the G2 is 39 percent and it's 16 percent for the Recovery. Do you see that? 01:06:04

A. That's what this slide says but, again, I don't know what this means without knowing where those percentages came from.

Q. What did Bard say under the comments section about that? 01:06:19

A. It says: G2 more tilt than RNF.

Q. All right. And now let's go to perforation. 36 percent for the G2, nine percent for the Recovery filter. Do you see that?

A. I do. 01:06:37

Q. So a higher percentage for the G2 compared to the Recovery; correct?

A. That's what the slide says.

Q. And Bard once again says: G2 more perforation than RNF or Recovery filter; agreed? 01:06:53

A. That's what it says on the slide, yes.

Q. And you talked about the MAUDE database earlier on direct examination. Do you remember that?

A. Yes, I do.

Q. That's a voluntary reporting system? 01:07:05

A. So it's voluntary for consumers and mandatory for manufacturers.

Q. And I think what you were telling us is that it's not a reliable source to determine rates of complications of the type that we're discussing here; correct? 01:07:23

A. I think what I said is that you can't use to it develop comparative data to compare one company's rates against another. 01:07:25

Q. And the reason it shouldn't be used is because there's a significant underreporting factor with MAUDE data; correct? 01:07:36

A. There is underreporting plus there isn't any denominator data so we don't know how to determine a rate.

Q. But the concern is that if somebody falsely relies on MAUDE data, there could be a false sense of security when it comes to the safety of the filter because the adverse events represented in the data bank may only be the tip of the iceberg. Agreed? 01:07:59

A. I don't think I would agree with that, no.

Q. Well, it's different than rates. What's the difference between a MAUDE data -- the underreporting versus an actual rate? 01:08:14

A. I'm not sure I understand your question.

Q. Well, with the EVEREST trial, those were actual rates; correct?

A. That's right, because we know how many patients and we know exactly what happened to those patients so we can calculate a rate in the EVEREST trial. 01:08:29

Q. And when people voluntarily report to the MAUDE databank, we know that that doesn't capture the real world adverse event rate for that device; correct? 01:08:45

A. I think it's well-known that there is some amount of underreporting in the MAUDE database. I think that's correct, yes. 01:08:47

Q. So a manufacturer should never say, wow, look at the MAUDE database; it looks great for us to bolster its safety profile; correct? 01:08:56

A. I mean, I don't think that that should be construed as an absolute determination of a -- the safety profile of the device but it's not perfect data but sometimes it's the only data we have. 01:09:14

Q. But, for example, with EVEREST we've got actual data; correct?

A. We have data from a controlled clinical environment which is different than what is going to necessarily happen in the real world. 01:09:27

Q. Right. And if Bard had continued that study, we would have seen whether those rates continued to trend either up or whether they leveled off, for example?

A. Yes, if the study had continued, we would have had more data, that's certainly true. 01:09:42

Q. And Bard did not do that. Agreed?

A. That's right, Bard did the study that FDA agreed it needed to do.

Q. All right. But Bard could have continued that study on its own if it had wanted to? 01:09:54

A. If Bard believed that there were additional questions that needed to be answered, yes, they certainly could have continued the study. 01:09:57

Q. All right.

MR. JOHNSON: You can take that down, Greg. 01:10:04

BY MR. JOHNSON:

Q. Let's talk a little bit more about what Bard gave or didn't give to the FDA; okay?

A. Okay.

Q. I realize that the answer to those questions is based on what Bard gave you; correct? 01:10:17

A. I can only form my opinions based on the information that is available to me, that is certainly correct.

Q. And the information that was given to you did not demonstrate that Bard told the FDA, before the Recovery filter was cleared and before the G2 filter was cleared, that their migration-resistance testing was based on flawed performance standards. Did you see that? 01:10:30

A. No. I'm not aware of any evidence of that, no.

Q. Did you see any evidence that Bard gave to the FDA any information that its consultant had found, as of December 17 o 2004, that the Recovery filter was worse than its own Simon Nitinol filter? 01:10:51

A. I'm not exactly sure what you're talking about.

Q. Well, did you see any evidence that Bard had provided to 01:11:18

the FDA its own internal data that the death rate associated with the Recovery filter had a relative differential of being 460 percent higher compared to all other filters, including the SNF, the Simon Nitinol filter? Did you see that? 01:11:20

A. Is that data that came from the health hazard evaluation? 01:11:44

Q. I'm just asking whether that data, did you see whether that data was ever conveyed by Bard to the FDA?

A. As I sit here today, I don't remember seeing that information being sent to FDA.

Q. Did you see whether Bard had conveyed to the FDA that the Recovery filter had a relative rate for migration that was 440 percent higher compared to all other filters, including Bard's own Simon Nitinol filter? 01:11:59

A. So I don't know what a relative rate is.

Q. Did you see where they conveyed that there was a 440 percent higher rate of migration for the Recovery filter compared to all other filters? Did you see that? 01:12:22

A. I'm not sure what information you're talking about so I don't know why Bard would have given that to FDA.

Q. You don't think the FDA would be interested in that? 01:12:39

A. I think FDA is interested in valid scientific interest evidence about the performance of the device but I'm not aware of the data you're talking about.

Q. Did you see any evidence that Bard had conveyed to the FDA that the Recovery filter had a relative rate for perforation of 01:12:55

the vena cava 410 percent higher than all other filters, including the Simon Nitinol filter? 01:13:00

A. So I'm not aware of the term "relative rate" being a regulatory term.

Q. But if a document uses that phrase, I guess -- that wasn't given to you? You haven't seen it? 01:13:13

A. I have seen a report from one of the plaintiff's experts that talks about relative rates but I'm not exactly sure what document you're talking about.

Q. Have you seen any evidence in the materials given to you by the Bard lawyers that the Recovery filter had a relative rate for fracture that was 530 percent higher compared to all other filters, including Bard's own Simon Nitinol filter? 01:13:34

A. Once again, I'm not sure what you mean by relative rates and I'm not sure what document you're talking about. 01:13:56

Q. All right.

Dr. Murray Asch, do you know who he is?

A. Yes, I do.

Q. Who is he?

A. So he was the investigator of a clinical study that was done and the data from which was used to support the initial clearance of the retrievable indications for the Recovery filter. 01:14:09

Q. All right. And have you been provided with Dr. Asch's recent deposition? 01:14:25

A. I have reviewed Dr. Asch's deposition so, yes, I believe I've seen his most recent one. 01:14:27

Q. And have you been provided the transcript that was given from that same seat to this jury last week?

A. I may have been but I haven't -- if I have, I haven't reviewed it. 01:14:40

Q. And just to remind everybody, I believe that the Recovery filter used the Simon Nitinol filter as its predicate device; correct?

A. The original Recovery filter used the Simon Nitinol filter. The retrievable one I believe used the permanent Recovery as the predicate. 01:14:55

Q. All right. Are you aware that Dr. Asch has testified that his study, his retrievability study, was not designed to assess substantial equivalence between the Recovery filter and the Simon Nitinol filter? 01:15:18

A. I'm not aware of him saying that but studies aren't usually designed to assess substantial equivalence. That is a finding that FDA makes.

Q. Well, beyond that, do you recall reading in his testimony that his study, in fact, did not establish substantial equivalence between the Recovery filter and the Simon Nitinol filter? 01:15:32

A. So I don't believe that was the purpose of the study. The purpose of the study was to evaluate the performance of the -- 01:15:49

the clinical performance of the Recovery filter. 01:15:52

Q. As a retrievability device; correct?

A. As a retrievable device, that is correct, yes.

Q. Let's get back to what was and was not provided to the FDA. Did you see any evidence that Bard conveyed to the FDA 01:16:02 that the G2 filter had an unacceptable risk of caudal migration?

A. I believe that Bard provided the caudal migration data from the EVEREST study in the G2 clinical study report.

Q. Did you see where Bard conveyed to the FDA that the G2 -- 01:16:26 that they had determined on their own that the G2 had an unacceptable safety risk relative to caudal migration associated with the G2 filter?

A. So I am not aware of Bard communicating that result to FDA, no. 01:16:45

Q. Have you seen any evidence -- had Bard given you any evidence that it told the FDA that the G2 filter failed to meet its initial product specification regarding migration resistance compared to the Simon Nitinol filter?

A. Yes. That information was actually provided to FDA in the 01:17:03 510(k) submission. Bard indicated what the migration-resistance testing was and then talked about the fact that the -- that the more appropriate predicate device was the Recovery device and that, in fact, they had shown the Recovery -- that the G2 migration resistance was better than 01:17:24

Recovery which is what it was intended to show. So that was very much disclosed to FDA. 01:17:28

Q. So you believe that Bard told the FDA that the migration-resistance testing for the G2 filter was found to be worse than the Recovery filter? 01:17:42

A. No, was found to be worse -- let me be a little bit more clear. I have my Recovery and G2s confused a little bit.

So in the 510(k), Bard presented the results of the migration testing that was done for the G2 filter and they noted that originally the specification was that it needed to be shown to be equivalent I believe to the Simon Nitinol filter then that was actually an inappropriate specification and that -- so instead, they had changed the specification to say that they needed to show that it was improved over the Recovery filter and then they provided test results that show that indeed the G2 migration resistance was better than the Recovery filter. 01:18:00 01:18:18

Q. All right. And that was based on bench testing, was it not?

A. And that was based on the bench testing, yes. 01:18:30

Q. And are you aware that the bench testing that was done for these filters was a rigid PVC pipe?

A. So it was a rigid PVC pipe with some kind of sausage casing on the inside, yes.

Q. And you learned that when you became an expert in this 01:18:50

case, didn't you? 01:18:52

A. Not sure what you mean by I learned that.

Q. You didn't know that Bard only used a fixed PVC pipe with sausage casing when you were a deputy director of the FDA, did you? 01:19:04

A. The test methods for -- that Bard used were in the 510(k) submission so FDA -- I wasn't involved in the submissions but FDA would have been aware of the test method.

Q. Are you aware that there's been evidence in this trial that sausage casing does not replicate the human inferior vena cava? 01:19:17

A. Yes, I'm certainly aware of the fact that that particular test method does not fully represent the actual physiological conditions; but like many test methods, it represents the best we can do on a bench. 01:19:35

Q. And with respect to Exhibit 2052, which represents real people in the real world, if this comparative table is designed to show whether G2 has a better or worse ability to resist migration compared to the Recovery filter, this document indicates that caudal migration for the G2 filter, being 14 percent, is worse than the Recovery filter at three percent. Agreed? 01:19:59

A. No, because I don't believe that those percentages mean what you're saying they mean. I think those are percentages of something other than percentage of patients. 01:20:15

Q. Okay. Were you provided any evidence that Bard ever told the FDA that its medical monitor for the EVEREST trial believed that doctors -- I'm sorry. 01:20:18

Were you ever provided any evidence that Bard provided to the FDA that the medical monitor for the EVEREST trial, a Dr. Kandarpa, noted that there was an approximate 50 percent device complication rate in the patient study? 01:20:47

A. I think that information was actually provided to FDA. All of the complications and adverse events were in that clinical study report. 01:21:10

Q. The question is whether Bard told FDA that the medical monitor, Dr. Kandarpa, felt that there was a 50 percent complication rate in the patient study. Was that information provided to FDA?

A. I'm not sure what you mean by felt that there was a complication rate. There was a complication rate that was observed and that number was reported to FDA. 01:21:29

Q. 50 percent?

A. I think that that sounds about right. That includes minor and major complications. 01:21:42

Q. Did you see any evidence that Bard informed the FDA that Dr. Kandarpa was concerned about the number of device complications?

A. I did not see any communications about that, no.

Q. Did you see any communications from Bard to the FDA that 01:21:59

Dr. Kandarpa was concerned about the number of filter tilts indicated by the rate being higher than what he had observed in his own clinical practice? 01:22:02

A. So I didn't see any evidence that Dr. Kandarpa actually communicated that information to FDA. 01:22:19

Q. No, ma'am. I'm asking you whether Bard communicated Dr. Kandarpa's concern to the FDA.

A. So I'm not aware of any formal documents that indicate that Dr. Kandarpa shared those concerns with Bard.

Q. Have you seen any evidence that Bard ever told the FDA that Dr. Kandarpa expressed concern about the number of tilts being approximately 20 percent and he thought that Bard may want to consider a redesign of the G2 filter? 01:22:39

MR. NORTH: Objection, Your Honor. This is just hearsay he's repeating and no foundation. 01:23:01

THE COURT: What's your response, Mr. Johnson?

MR. JOHNSON: I'm just asking whether this information -- she saw any evidence that this had been provided to the FDA.

THE COURT: I know what you're asking. What's your response to there's no foundation for the facts you're putting in your question? 01:23:14

MR. JOHNSON: Judge, they have opened the door when they went into elaborate detail about what Bard gave to the FDA and how they reported accurately information to the FDA. I 01:23:26

think they have opened the door to this. 01:23:30

THE COURT: Are you assuming facts in evidence?

MR. JOHNSON: Yes, ma'am -- yes, sir.

THE COURT: You believe that that evidence has already been presented? 01:23:42

MR. JOHNSON: It has not been presented.

THE COURT: I'm going to sustain the objection.

MR. JOHNSON: Okay.

BY MR. JOHNSON:

Q. Would you agree with me that Bard, not the FDA, designed, manufactured, sold, tested and profited from this G2 filter that we're talking about? 01:24:07

A. Yes, I agree that is true.

Q. And Bard is responsible for ensuring the safety of the G2 Filter that was implanted in Ms. Booker? You would agree with that? 01:24:24

A. I would absolutely agree with that, yes.

Q. Ma'am, you've told us about your background and I know you are a doctor. You have a doctorate degree. Correct?

A. In biomedical engineering, yes. 01:24:46

Q. You are not a medical doctor?

A. No, I'm not.

Q. And you are not the kind of professional that implants G2 filters or removes them?

A. That is correct. 01:24:56

Q. Have you ever touched, felt, or handled a G2 filter? 01:25:01
A. Absolutely.
Q. You did that as your work as an expert in this case?
A. As an expert in this case, yes.
MR. JOHNSON: May I have one minute, Judge? 01:25:17
THE COURT: Yes.
MR. JOHNSON: Thank you, ma'am.
THE COURT: All right.
Redirect?

REDIRECT EXAMINATION 01:26:07

BY MR. NORTH:
Q. Dr. Tillman, I want to ask you just a few additional questions about the exhibits that were just admitted a few minutes ago.
MR. NORTH: If we could go to 7758, please? 01:26:21
And Your Honor, may we display?
THE COURT: Is that in evidence?
MR. NORTH: Yes, that's the one you just admitted.
THE COURT: All right. You may.
BY MR. NORTH: 01:26:38
Q. We were talking about this this morning. Can you tell us again what this guidance document pertains to?
A. So this is FDA's guidance document that provides information about how it determines whether a device is substantially equivalent to another device. 01:26:53

Q. And if we could turn to 7758.0009 of the document. Down below, that's towards the bottom, does the FDA explain the standard that it utilizes in evaluating substantial equivalence? 01:27:01

A. Yes, it does. 01:27:20

Q. And can you tell us what it states there?

A. Do you want me to read the entire paragraph?

Q. Yes, 510 -- that begins 510(k).

A. (Reading) So the 510(k) review standard substantial equivalence of a new device to a legally marketed predicate device differs from the PMA review standard reasonable assurance of safety and effectiveness. The 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness. Nonetheless, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review. 01:27:32 01:27:51

Q. Thank you.

Now, if you could turn next in that same document to .0030. And can you explain to us briefly what this chart is? 01:28:08

A. So this is a graphical representation of that slide, that demonstrative slide I showed you earlier, which is the thought process for determining how FDA determines substantial equivalence. So it basically is a flowchart that sort of turns 01:28:30

those words I gave you into boxes and decisions. 01:28:34

Q. If you would look over at the top right, the column that comes down that begins "Determine what questions"?

A. Okay.

Q. What is that having the FDA look at as a part of this evaluative process? 01:28:52

A. So this is talking about if you've got a device that has different technological characteristics so, for example, if you have a filter that has a slightly different design, one of the questions FDA has to ask is, do those differences raise different kinds of questions? 01:29:10

So, for example, if there was something about a design that raised a fundamental different scientific question. So let's say instead of the filter being made out of a material, a permanent material, let's say it was made out of something that dissolved over time. That would raise different kinds of questions because with the filters we have today, we don't think about what happens as they gradually degrade. 01:29:29

So FDA would find that to be a different type of question of safety and effectiveness; and if that occurs, then that device is found not substantially equivalent. And, in fact, if you recall, we talked about one filter that had a PMA way back at the beginning and the reason that filter actually had a PMA was because its design was so different that FDA determined that it raised new types of safety and 01:29:46 01:30:06

effectiveness questions and it needed a PMA. 01:30:09

Sorry, Richard, I can go on and on about this.

Q. Let's go on to Exhibit 7753.

MR. NORTH: Could we display this document also, Your Honor? 01:30:29

THE COURT: Yes.

BY MR. NORTH:

Q. Is this is another of the guidances that you were talking about this morning?

A. Yes. This is a guidance document that talks really about how does FDA think about benefits and risks when it's trying to determine if a new device is substantially equivalent to a predicate. 01:30:37

Q. Let's turn if we could to 7753.0007. What does the FDA say here as to whether, particularly under scope, whether the new device has to be identical to the predicate device? 01:31:07

A. So and this is what we talked about also earlier which is that the 510(k) review standard does not require a new device to be identical to a predicate device.

Q. Okay. Let's go on to the next page, 0008. Under Benefit and Risk Factors, about midway through the paragraph. What does the FDA say about making a determination as to substantial equivalence if there are differences? 01:31:32

A. So it says that FDA may make a determination that a new device is SE, which means substantially equivalent, to a 01:31:55

predicate device even if there are differences in the benefits and risks of the new device. So this means that a device as we talked about earlier, a device can have different benefits and different risks but still be substantially equivalent as long as the overall risk-benefit profile is equivalent to the predicate device. 01:31:59 01:32:13

Q. And if we could go to the next page under Increased Risk/Increased Benefit, what does the FDA say there with regard to a situation where the new device being proposed has in some ways greater risk of complications than the predicate device? 01:32:32

A. So the guidance says that if the risks associated with the new device increase as compared to the predicate, FDA may still determine that the new device is SE to the predicate if, for example, FDA finds from a review of the new device's performance data that there are also increased benefits with the new device as compared to the predicate device. 01:32:52

Q. And then let's go to 0014 in the same document. What does the agency say here about innovative technology?

A. So FDA says that when a new device has technological improvements that are important for public health, we may accept greater uncertainty in an assessment of benefits and risks as compared to the predicate device than for most established technologies in order to facilitate patient access to these innovative technologies if FDA's overall assessment is sufficiently balanced by other factors to support a 01:33:24 01:33:44

determination that the new device is SE to the predicate device. 01:33:47

Q. From your review of the history of IVC filters and the regulatory process, was the adoption of Bard's type of retrievable filter an innovative change? 01:34:04

A. I believe that it was an innovative change. I believe it reflected an additional opportunity for patients to have access to filters who may not have had them if they were only indicated for permanent use.

Q. Let's turn now if we could to Exhibit 5126 which was admitted at the top of the hour. 01:34:22

MR. NORTH: And could we display 5126, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

Q. And remind us once again what 5126 represents as far as a guidance document from the FDA? 01:34:39

A. So we talked before lunch about the fact that when FDA down-classified IVC filters, they established special controls and those were the things that a guidance document that lays out what kinds of testing and information is necessary in order to mitigate the risks to an acceptable level. 01:34:58

And this is the special control guidance document for IVC filters?

Q. Let's turn to beginning with 5126.0007. Does the guidance document here for IVC filters summarize complications that have 01:35:35

been found with these devices? 01:35:40
A. Yes, it does.
Q. And, again, what year was this published?
A. 1999.
Q. Was that prior to the time the Recovery filter was 01:35:48
submitted to the FDA as a 510(k)?
A. Yes, it was.
Q. And the same with the G2?
A. Absolutely, yes.
Q. And then going on to the next page, what are some of the 01:35:59
complications -- what sorts of things are the FDA saying about
complications here?
A. So these are the complications that FDA believes are known
to exist for IVC filters. The first group were complications
associated with the device delivery process and then FDA goes 01:36:20
on to talk about how those complications can affect the filter.
So they can deform it, they can fracture it, it can result in
the filter being placed improperly. And then, lastly, FDA
talks about other types of potential complications including
the filter getting engaged in the introducer so you can't get 01:36:43
it out, that it may be difficult for the practitioner to insert
the device. And then FDA talks about filter legs break
breaking, deployment problems and other problems with the
filter potentially fracturing as known complications of these
devices. 01:37:01

Q. Let's go on to 0009 in the same document. Does the FDA recognize in the guidance document that, unfortunately, death in a number of cases is a complication associated with IVC filters? 01:37:02

A. Yes. FDA does recognize that. 01:37:17

Q. And does it recognize that cephalic migration of a filter to the heart after placement is a known cause of death with regard to IVC filters?

A. Yes, it does. The guidance document indicates that FDA is aware of that potential adverse event. 01:37:36

Q. And this was published before the Recovery filter was ever introduced to the market?

A. Yes, it was.

Q. If we could, look at the next paragraph on that same page, filter migration. And what does the FDA say about migration in general in that first sentence? 01:37:50

A. FDA notes that minor filter migration in the caudal or cephalic direction is commonly reported and does not appear to be associated with clinically significant events.

Q. Let's go to the next page and look at caval penetration. 01:38:27 Why does the FDA indicate that determination of penetration is complicated?

A. Well, I'm not an interventional radiologist but it's my understanding that due to a number of factors, it sometimes may be difficult to determine whether or not parts of the filter 01:38:54

have actually penetrated the wall of the vena cava or not and that it may be just due to things that are seen on imaging that may not actually reflect caval penetration. 01:38:58

Q. And then let's go to the next paragraph dealing with filter tilting. And what does -- why is the agency suggesting that filter tilting, its significance may be controversial? 01:39:14

A. What FDA is saying here is that there is a theoretical loss of filtering efficacy of a filter when it's tilted or angulated. So if you've got the filter and it's supposed to go this way and it's turned on the side, it potentially may be less effective at capturing clot. 01:39:40

Q. And, again, did the publication of this guidance predate the introduction of any of Bard's retrievable filters?

A. That is correct.

Q. If we could turn to the last page, 00112, what is this particular part of the guidance? It's referenced as an attachment. What is its significance? 01:40:01

A. These are FDA's recommendations about what information should be included in the instructions for use and the labeling for the device. So the first part are the indications for use, what is the patient population of the device is intended to be used in. And then FDA goes through and explains some of the common contraindications and warnings that need to be included in filter labeling. 01:40:20

Q. And this was published as a part of the guidance for IVC 01:40:38

filters? 01:40:42
A. Yes, it was.
Q. Now if we could turn to Exhibit 7795 which was admitted.
MR. NORTH: And Your Honor, could we have 7795 displayed? 01:40:56
THE COURT: Yes.
BY MR. NORTH:
Q. Tell us again, Dr. Tillman, what 7795 is?
A. So this is a screen shot of FDA's MAUDE -- the portal into FDA's MAUDE database. This is an FDA public website so anybody 01:41:12 can go into this website and search FDA's adverse event database.
Q. And does the description of the database contain a number of bullet points about that database?
A. Yes, it does. If you look sort of underneath the section 01:41:30 where you can put in the search terms, in this language FDA explains some of the limitations of the MDR data.
Q. Let's look at the second bullet point there particularly, what the FDA says about the use of the database.
A. So FDA notes that MDR data alone cannot be used to 01:41:50 establish rates of events, evaluate a change in event rates over time, or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices. 01:42:10

Q. Based upon that limitation expressly stated by the FDA, do you think there's any way that a medical device manufacturer could include comparative rate information based upon MAUDE data in its instructions for use? 01:42:17

A. No. I think given the limitations in the MDR data as noted here, it would be inappropriate to include that information in labeling. 01:42:34

Q. Thank you.

MR. NORTH: That's all the questions I have.

THE COURT: Mr. Johnson, you didn't have a chance to cross on this material. If you would like to, you may. 01:42:46

MR. JOHNSON: Please.

RECROSS - EXAMINATION

BY MR. JOHNSON:

Q. Ma'am, you used the term "risk-benefit" a couple of times. Do you remember that? 01:43:14

A. Yes.

Q. And obviously that involves an analysis where, for example, a doctor who wants to use a filter who wants to use the safest filter needs to balance the risks against the safety and efficacy of that device. Agreed? 01:43:26

A. Yes, I would agree with that I think.

Q. And many of these documents that we have been talking about predate the innovation of the Bard G2 filter. Agreed?

A. Do you mean the FDA guidance document? 01:43:47

Q. Yes. 01:43:50
A. Certainly the IVC filter guidance document predates it, yes.
Q. And as medicine marches ahead, we learn more about risk benefits. Risk-benefit, obviously, evolves over time, does it 01:44:00
not?
A. Absolutely.
Q. And certainly you don't want or Bard -- you would not want a Bard filter to have a safety profile where the risks exceed the benefit. Agreed? 01:44:15
A. I would agree, yes.
Q. And I gather you haven't been provided with the testimony that has been given by a Dr. Fred Rogers in this case, have you?
A. No, I have not. 01:44:29
Q. You're not aware that Dr. Rogers is a trauma surgeon who surveyed 30 million high-risk trauma patients and determined filters do not save lives? You're not aware of that, are you?
A. I am not aware of any research in that area, no.
Q. Certainly that is the kind of information that, as 01:44:53
medicine moves forward, influences the risk-benefit analysis. Agreed?
A. I would agree that risk-benefit needs to take into account what we learn, yes. I would agree with that.
Q. And I think I heard you mention a few minutes ago that it 01:45:09

wouldn't be appropriate to put in the IFU comparative rates between the G2 filter and other filters. Do you remember that? 01:45:13

A. Not based on MDR data.

Q. All right. But there's nothing wrong with a manufacturer telling doctors, either in its IFU or verbally, we have a concern that our filter has a safety profile worse than our own existing filter, for example, the Simon Nitinol filter? 01:45:31

A. It would be unusual for a medical device manufacturer to make that kind of statement. I think that, you know, clearly there is information in the G2 IFU about its safety profile based on the EVEREST study. 01:45:57

Q. There would be nothing wrong with Bard putting in its IFU or telling its sales force to inform doctors that we have determined the safety profile of our G2 filter is worse than the Simon Nitinol filter? Nothing wrong with that; correct? 01:46:22

A. I can't see any FDA regulatory reason that would prevent a company from doing that.

Q. Can you imagine for one second what would happen to sales of the Bard G2 Filter if that kind of information was provided by Bard to doctors? 01:46:42

A. Is that a question?

Q. Yes.

A. I can't imagine that that would be very good for Bard sales.

Q. They would lose money, wouldn't they? 01:46:58

A. Once again, certainly that would not be the kind of information I would expect a company to put into its labeling. 01:46:59

Q. Thank you.

THE COURT: Anything further, Mr. North?

MR. NORTH: Nothing further, Your Honor. 01:47:10

THE COURT: All right. Thank you. You can step down.

THE WITNESS: Thank you.

(Witness excused.)

MR. NORTH: At this time, Your Honor, the defendants would call Ms. Shari Allen O'Quinn to the stand, please. 01:47:20

THE COURT: All right. Ladies and gentlemen, if you want to stand up for a minute while she's coming in, feel free.

(SHARI ALLEN O'QUINN, a witness herein, was duly sworn or affirmed.) 01:48:00

COURTROOM DEPUTY: Could you spell your first name for us, please.

THE WITNESS: Shari, S-H-A-R-I. O'Quinn, O-Q-U-I-N-N.

COURTROOM DEPUTY: Thank you, ma'am. Please come have a seat. 01:48:22

DIRECT EXAMINATION

BY MR. NORTH:

Q. Good afternoon, Ms. O'Quinn. How are you?

A. Good. How are you? 01:48:46

Q. Were you at one time an employee of Bard? 01:48:49
A. Yes.
Q. And how long did you work at Bard?
A. I worked at Bard for about four years.
Q. And what years were those? 01:48:59
A. 2003 to 2007.
Q. And when we say Bard, what particular part of Bard were you working at?
A. I was working at Bard Peripheral Vascular.
Q. And is that here in Tempe? 01:49:14
A. Yes, it is.
Q. And what was your title at Bard?
A. My title at Bard, the last title was Director of Clinical and Regulatory and before that I was Manager of Regulatory.
Q. And please describe for the jury your roles and 01:49:32
responsibilities at Bard Peripheral Vascular as the Director of Clinical and Regulatory?
A. My responsibilities there were to lead the clinical and the regulatory functions and what that means is my group did the clinical studies that were needed to support the devices 01:49:50
and also summarize the data and submit that to FDA or other regulators around the world to get the products approved.
Q. What sorts of products did you work on while at Bard Peripheral Vascular?
A. A variety of products, mostly peripheral vascular 01:50:09

products. And what that means are vena cava filters, stents, angioplasty balloons and other products like that. 01:50:13

Q. Describe for the jury the level and amount of interaction you had with the FDA while working at Bard.

A. The interaction I had with FDA was very extensive. We spoke with them -- I most of time personally would speak with them very frequently or members of my team would interact with them. But it was frequent. 01:50:32

Q. In the decade or so since you left Bard, what sort of work have you done? 01:50:51

A. I worked in the same area working with similar companies all with cardiovascular implantable devices.

Q. Are you presently employed?

A. Yes, I am.

Q. And what type of work do you presently do? 01:51:02

A. I am currently the Vice President of Clinical and Regulatory and Quality for W.L. Gore that's based here in Arizona.

Q. Can you describe for the jury your educational background?

A. Yes. I have a bachelor's from the University of Virginia. 01:51:28

Q. And what was your major as an undergrad?

A. Biology and chemistry.

Q. How did you end up in the medical device field, Ms. O'Quinn?

A. When I was a student, I thought about going to medical 01:51:45

school but I started working as a research assistant doing clinical research and really enjoyed the clinical research side and seeing new products come to market and decided that I would stay on the research and then later got involved in the regulatory field once I started working in consulting. 01:51:46 01:52:04

Q. When you started work at Bard, did you start immediately working on projects with regard to IVC filters?

A. Not immediately. I was working primarily on the stent and stent graph programs; but very soon after joining Bard, I got involved in the IVC filters. 01:52:27

Q. Were you involved in any of the 510(k) submissions to the FDA regarding the Recovery filter?

A. Yes, I was.

Q. And what about with regard to the G2 filter?

A. Yes. 01:52:49

Q. Now we've already heard a great deal of testimony I don't want to repeat but are you generally familiar with the 510(k) process?

A. Yes, I am.

Q. Do you still work with the 510(k) process today in your job? 01:53:01

A. Less frequently with 510(k). They are mostly PMA devices.

Q. But do you still work with the FDA in your job?

A. Yes.

Q. In your experience, how rigorous a process was the 510(k) 01:53:14

process for the inferior vena cava filters? 01:53:25

A. For a 510(k), it was very rigorous. The FDA often required clinical data, they required extensive animal and engineering testing for those types of devices. It was much more so than for some other 510(k) devices. 01:53:43

Q. Did the agency require nonclinical and bench testing for the submissions?

A. Yes, they did.

Q. Did the agency require animal testing?

A. Yes. 01:53:56

Q. In your experience, if the FDA had questions regarding Bard's submissions, would and could they ask questions?

A. Yes, they would.

Q. Did they do so with regard to the IVC filters?

A. Yes, they did. 01:54:09

MR. NORTH: If we could pull up 5189.

BY MR. NORTH:

Q. Can you identify for the jury what 5189 is?

A. Yes. That's the Recovery filter special 510(k) submission. 01:54:45

Q. And this was submitted, as I understand it, before you began work at Bard?

A. Yes, that's correct.

Q. When you took over the supervision of the Regulatory Department at Bard Peripheral Vascular, did you become familiar 01:54:59

with the documentation that had been submitted prior to your time with regard to the Recovery filter? 01:55:03

A. Yes, I did.

Q. And do you recognize this 510(k) submission as one that Bard had submitted? 01:55:16

A. Yes, I do.

Q. And was a copy of this submission kept in your department's files as a part of the normal course of business?

A. Yes, it was.

Q. And were you actually employed at Bard at the time the G2 submissions were made? 01:55:26

A. Yes.

Q. And did you and your department refer back to the Recovery filter submissions in working on the G2 submissions?

A. Yes, we did, frequently. 01:55:42

Q. And so would you have consulted this document and others like it?

A. Yes.

MR. NORTH: Your Honor, at this time we would tender 5189. 01:55:50

MR. O'CONNOR: Your Honor, I think there was an agreement that --

THE COURT: I can't hear you, Mr. O'Connor. A little louder please.

MR. O'CONNOR: I think we're agreeing to submit this 01:56:15

subject to objections that we're going to be talking about over the weekend. 01:56:17

MR. NORTH: That's fine, Your Honor.

THE COURT: Okay. This was one of the ones we mentioned last night? 01:56:25

MS. MATARAZZO: Yes, Your Honor. There's going to be a bunch of them for this witness.

THE COURT: That's fine. We'll admit 5189 subject to those discussions over the weekend.

MR. NORTH: Certainly, Your Honor. 01:56:33

(Exhibit Number 5189 was admitted into evidence.)

BY MR. NORTH:

Q. And did the FDA eventually clear the Recovery filter?

A. Yes.

MR. NORTH: If I could look at 5177. 01:57:02

BY MR. NORTH:

Q. And have you seen 5177 before?

A. Yes, I have.

Q. And what is that document?

A. This document is the cover letter for the 510(k) for the Recovery filter. 01:57:24

Q. And did this permit the company to sell the Recovery filter as a permanent device?

A. Just a minute. Let me take a look at this.

Yes. This is the FDA 510(k) clearance letter. 01:57:48

MR. NORTH: Your Honor, at this time we would tender 5177. 01:57:54

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit Number 5177 was admitted into evidence.) 01:58:05

BY MR. NORTH:

Q. Now, did Bard submit thereafter, according to your knowledge, an additional 510(k) to have the Recovery filter cleared for a retrievable indication?

A. Yes. 01:58:23

Q. If we could look at Exhibit 5169.

And do you recall when in 2003 you began or was it 2004 you began with Bard?

A. I would have to verify but I believe it was 2003.

Q. And do you recall whether you had actually started work at the time this was -- the retrievable application was filed? 01:58:45

A. I believe that I had started either just before it was submitted or during the time of the review.

Q. But you became familiar, during the course of your duties particularly heading up the entire Regulatory Department, with this, didn't you? 01:59:06

A. Yes, absolutely.

Q. And this is a business record of the company?

A. Yes.

\\\

MR. NORTH: Your Honor, at this time we would tender 5169. 01:59:16

MR. O'CONNOR: Your Honor, this is one that is subject to -- admitted subject to our objections.

THE COURT: Subject to the discussion? 01:59:24

MR. JOHNSON: Subject to the discussion.

THE COURT: All right. We'll admit it for that -- well, we will admit it but subject to the discussion that will happen between the parties.

(Exhibit Number 5169 was admitted into evidence.) 01:59:33

THE COURT: And incidentally, ladies and gentlemen, it's being admitted but the parties are going to have a discussion about whether or not there are portions of the exhibit that should not come into evidence. So you can write it down if you are writing it down, so it's in evidence, but it may be limited in some way later. The parties are going to talk about it. 01:59:44

All right. Go ahead.

BY MR. NORTH:

Q. And this is just the cover page that you're looking at right here; correct? 01:59:53

A. Yes.

MR. NORTH: May we display that for the jury?

THE COURT: Yes.

\\\

BY MR. NORTH: 02:00:02

Q. My understanding is this entire submission, which I believe is being put in the notebook here, is stacks and stacks of pages; correct?

A. Yes. It's a lot of data. 02:00:10

Q. And what sort of data did it contain?

A. It contained information describing the device. It was engineering testing that was done to test the product as well as animal testing and -- I would have to look at the cover page but it was a lot of extensive testing data that was included. 02:00:34

Q. Let's look at Exhibit 5197 if we could.

Could you identify what 5197 is?

A. This is the FDA letter granting clearance for the 510(k) to market the Recovery filter for the retrievable indication.

Q. And, again, was this issued on or about around the time you became employed by the company? 02:01:15

A. Yes.

Q. Now, were you working as the head of Regulatory Affairs for the company once the Recovery filter went to market and there began to be reports of migration deaths with regard to the device? 02:01:42

A. Yes.

Q. Was Bard concerned upon receiving -- in your view, was the company concerned when receiving reports of complications, including those reports of deaths? 02:02:02

A. Yes, absolutely. We took it very seriously and as those reports came in, there was a large team of people that would evaluate the information. 02:02:05

Q. Do you recall in February of 2004 Bard learning for the first time that a patient had experienced a Recovery filter migration where the filter went to the patient's heart? 02:02:23

A. Yes, I do.

Q. And that that patient, unfortunately, passed away?

A. Yes.

Q. Are you familiar with that incident and the investigation that was done of that incident? 02:02:40

A. Yes, I am.

Q. Can you tell the jury what was done?

A. We launched a thorough root cause evaluation where we tried to understand what caused the migration and we conducted a lot of -- we actually had a lot of discussions with physicians. We got physician panels together to collect information from them to try to understand what happened and did additional testing to try to understand what happened. But we took it very seriously, met frequently to understand what contributed to that event. 02:02:52 02:03:21

Q. Were you involved in the investigation of that incident?

A. Yes.

Q. Did Bard Peripheral Vascular send people to Miami where it occurred to investigate? 02:03:40

A. Yes, they did. I did not go but others did. I said I did not personally go but I was aware of the people from Bard who did go. 02:03:41

Q. And when the people that did go down to Miami, did they come back and meet with you and others to report on what they had learned about the incident? 02:03:54

A. Yes, they did.

Q. Do you recall if the patient who died in the Miami incident was a morbidly obese patient?

A. I seem to recall that they were, yes. 02:04:09

Q. And do you recall anything concerning what was discovered about the clot found with the filter in the patient that died?

A. Yes.

MR. O'CONNOR: Objection, Your Honor. This is lack of foundation in terms of -- this is not a medical -- this is not a medical expert or witness. 02:04:27

THE COURT: Overruled.

MR. O'CONNOR: Also hearsay, Your Honor.

THE COURT: Well, reask the question in a way that does not call for hearsay. 02:04:43

So the objection is overruled. I don't think the answer necessarily is hearsay but I want to make clear that's not being elicited.

BY MR. NORTH:

Q. Did you receive some information as a part of being on the 02:04:55

investigation team regarding the size of the clot involved in the Miami incident? 02:04:57

A. Yes, I did.

Q. And tell us, not by quoting conversations, but how generally did you receive that information? 02:05:07

A. I received that information from the people who were at the -- who visited the physician and had discussions with them and they gave us images from this patient's clot and it was -- it was very large. I recall that it was over 20 centimeters which was very large. 02:05:32

Q. And as a part of that investigation, were those photographs kept in the investigative file?

A. Yes, they were.

Q. If we could show you 5534. Do you recognize that photograph? 02:05:53

A. Yes, I do. That is the clot from that case.

Q. Are you able to see the filter with the clot in that instance?

A. Yes, I can, in the upper left. The small portion there is the filter and then you can see that the clot is very, very large, significantly larger than even the filter. 02:06:07

Q. Were those photographs the ones that you talked about being obtained during the investigation?

A. Yes, they were.

Q. Were they maintained as a part of Bard's investigative 02:06:22

file regarding this incident? 02:06:27

A. Yes.

MR. NORTH: Your Honor, at this time we would tender 5534.

MR. O'CONNOR: No objection. 02:06:36

THE COURT: Admitted.

(Exhibit Number 5534 was admitted into evidence.)

MR. NORTH: Could we display this to the jury, Your Honor?

BY MR. NORTH: 02:06:57

Q. And can you point out again, now that this is displayed to the jury, exactly where the filter is in this photograph of this clot?

A. Yes. If you look at the upper left, you'll see the tip of the filter extending beyond the edge of the clot in the upper 02:07:08 left and you'll see the wires of the filter in about the middle part of the upper section of the clot. But you can see that the clot extended down significantly below this. It was very, very large.

MR. NORTH: Your Honor, my caretakers tell me I 02:07:29 forgot to tender 5197, which was the last exhibit, the clearance letter that we had identified.

THE COURT: 5197, which was the clearance letter. Any objection to that?

MR. JOHNSON: Was that the one before this? I have 02:07:46

no objection. 02:07:48

THE COURT: All right. 5197 is admitted.

(Exhibit Number 5197 was admitted into evidence.)

MR. NORTH: You can take that down now.

BY MR. NORTH: 02:07:53

Q. What else did Bard do to address these reports of migration with the Recovery filter?

A. We did a very thorough investigation. We got our engineers. We had engaged physicians as medical experts to give us input over time. We also conducted surveys, we got 02:08:13 physician panels together. We communicated frequently with the FDA to share this information with them as well.

Q. Now, during this time, did Bard decide to update its instructions for use?

A. Yes. 02:08:40

Q. Did it also decide to send any sort of communication to physicians about these incidents?

A. Yes, we did. We updated the IFU and shared that with the FDA and then sent a letter to physicians and shared that information with physicians in the letter. 02:08:57

MR. NORTH: If we could look at 5196, please.

Q. Who was Mary Edwards?

A. Mary Edwards was my supervisor at the time that I started at Bard.

Q. And so you reported to her? 02:09:26

A. Yes, I did. 02:09:27

Q. And when she left the company, did you essentially take over her role in supervising regulatory affairs?

A. Yes, I did.

Q. Is this letter, 5196, a communication that Ms. Edwards made to the FDA regarding changes to the IFU? 02:09:40

A. Yes. This is the letter that Mary submitted to FDA providing them a copy of the changes to the IFU.

Q. Did it also provide them with copy with a proposed letter to clinicians about the modifications? 02:10:05

A. Yes, it did.

Q. And were you familiar generally with this letter going out?

A. Yes, I was.

MR. NORTH: Your Honor, at this time we would tender 5196. 02:10:21

MR. JOHNSON: This one is subject to the agreement, Your Honor.

THE COURT: All right. This is admitted subject to further discussion of the parties. 02:10:28

(Exhibit Number 5196 was admitted into evidence.)

BY MR. NORTH:

Q. And did the company hear back from the FDA?

Well, let's look at 5195 if we could.

A. I would need to verify the correspondence. I believe so 02:10:45

but I would want to verify. 02:10:48

BY MR. NORTH:

Q. Let's look at 5195. Does this appear to be comments or a response from the FDA to Ms. Edwards' letter in October of 2004? 02:11:19

A. Yes, it is. That's the response from FDA and they said that they approved the language in the Dear Doctor letter with some additional comments.

MR. NORTH: Your Honor, at this time we would tender 5195. 02:11:33

MR. O'CONNOR: I think this one is subject to the same agreement, Your Honor.

THE COURT: All right. Admitted subject to further discussion of the parties.

(Exhibit Number 5195 was admitted into evidence.) 02:11:41

MR. NORTH: Could we display this to the jury, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

Q. If we could look down about the third sentence beginning "The language." 02:11:52

So did the FDA actually provide comments on the Dear Doctor letter that Bard intended to send out to physicians regarding the changes to the instructions for use?

A. Yes. 02:12:20

Q. Did Bard comply with the FDA's directions and make those changes? 02:12:21

A. Yes.

Q. And did Bard send this letter out and also revise the IFU as it had discussed with the FDA? 02:12:31

A. Yes.

Q. Why did Bard want FDA's input on this letter?

A. We wanted to be very proactive with the FDA to make sure that we were being transparent with them about the rates. We wanted to make sure that they were comfortable with the language, that we had appropriately disclosed the risks to physicians and we wanted to make sure that they approved the content. 02:12:52

MR. NORTH: Let's look at 5001, please.

BY MR. NORTH: 02:13:25

Q. Did you identify 5001 for us?

A. Yes. This is the Dear Doctor letter that we sent to physicians.

Q. And was that sent in approximately December of 2004?

A. I don't see the date on the letter to confirm but I recall that it was about that time. 02:13:44

MR. NORTH: Your Honor, at this time we would tender 5001.

MR. O'CONNOR: No objection, Your Honor.

THE COURT: Admitted. 02:14:04

(Exhibit Number 5001 was admitted into evidence.) 02:14:04

BY MR. NORTH:

Q. Is this Dear Doctor letter -- oh.

MR. NORTH: Could we display this to the jury, Your Honor? 02:14:15

THE COURT: Yes.

BY MR. NORTH:

Q. Does this specifically advise physicians what has been changed in the instructions for use based upon the clinical reports? 02:14:32

A. Yes, it does. It indicates that -- it actually summarizes the changes to the IFU and indicates how the warnings and the precautions in the safety sections of the IFU were updated specifically to identify the risks of fracture and migration and some other procedural information that we wanted to make 02:14:57 the physicians aware of that was important.

Q. Was this the only communication the company made regarding the Recovery filter and possible migration incidents to physicians?

A. I don't recall if there was some individual communications 02:15:22 with physicians but we did do a second letter later, a Dear Colleague letter, that also went out to physicians.

MR. NORTH: Let's look at 5247 if we could.

BY MR. NORTH:

Q. Do you recognize this document? 02:15:53

A. Yes. That's the Dear Colleague letter that I just mentioned. 02:16:05

Q. And before you sent -- the company sent this letter out, did you have discussions with the FDA about the fact that the company was going to send this letter out to physicians? 02:16:14

A. Yes, we did.

MR. NORTH: Your Honor, at this time we would tender 5247.

MR. JOHNSON: Your Honor, we did not see this on their list -- oh. Never mind. I apologize. We don't have any objection. 02:16:31

THE COURT: All right. 5247 is admitted.

(Exhibit Number 5247 was admitted into evidence.)

MR. NORTH: Could we publish it?

THE COURT: You may. 02:16:44

BY MR. NORTH:

Q. If we would look in the first sentence at the paragraph that begins "Over the past two years." And going to the end of that paragraph. Could you tell us what the company advised physicians about with regard to the Recovery filter here? 02:17:21

A. Yes. We advised them about the risk of filter migration and that some of them had been associated with interventions and death and we shared that although those events had occurred, they were below the rates that had been reported in the Society of Interventional Radiology guidelines and that the 02:17:48

majority of those events were associated with patients who were morbidly obese. 02:17:56

Q. Let's turn to the next page of that document, and under the side paragraph called sizing, had the company seen most of these Recovery filter migration incidents occurring in morbidly obese patients? 02:18:22

A. Yes. That is true, correct. And the majority of the diameters of the vena cavas were above 28 millimeters.

Q. And why was that important, that most of the migrations were seen occurring in people with inferior vena cavas with greater diameters than 28 millimeters? 02:18:42

A. Because of the dimensions of the filter, it was difficult for the filter to expand beyond that amount and also, the patients could produce incredible amount of intraabdominal pressure that could put additional force on the vena cava filter. 02:19:07

Q. So in this letter under Sizing, did the company specifically remind physicians about that limitation for the use of the Recovery filter?

A. Yes, we did and we bolded it in the letter to make sure that it was really clear. 02:19:24

Q. Now, let's look at the next section on that same page, Anticoagulation Regimen. Did the company specifically advise doctors to do anything with regard to returning patients to anticoagulation? 02:19:44

A. Yes. We noted that the patient should be returned to their anticoagulation therapy as soon as it was deemed safe. 02:19:46

Q. And turn to the next page, page three of this document. Did the company also encourage physicians to report any adverse events both to the company and to the FDA? 02:20:07

A. Yes, we did. We provided the FDA contact information and our contact information and reiterated to the physicians that it was very important for them to report the events to both us and to the FDA.

Q. Now, when the company, during your time there, would send out a letter like this, a Dear Colleague letter or a Dear Doctor letter like the previous one we saw, what sort of steps did the company take to ensure that this got the widest distribution or dissemination possible? 02:20:28

A. We looked at our entire customer database of anyone that had purchased the product and sent the product out to those physicians and we tracked the delivery of those letters to make sure that they were delivered. 02:20:47

Q. Now, over the course of this time period in the late 2004, early 2005 time frame, were you having a number of conversations with the FDA? 02:21:24

A. Yes, I did. I had frequent communications with the FDA.

Q. And did you have communications that specifically discussed the reports of migration with regard to the Recovery filter that the company was receiving? 02:21:41

A. Yes, I did. I had frequent phone contacts with the FDA where --

MR. O'CONNOR: Objection, Your Honor. This is hearsay.

THE WITNESS: I have contact had reports -- 02:21:52

THE COURT: Hold on, please.

Overruled so far. There has been nothing said about the content of the conversations.

BY MR. NORTH:

Q. Just generally, describe what these conversations were, the topics of these conversations. 02:22:00

A. Yeah. The topics of the conversations were to update FDA on the current rates. We would always talk about the rates. We would talk about where we were in the investigation and any additional work that we were doing like feedback from 02:22:17 physicians or any internal testing that we were doing, we would share that with the -- I would share that with the FDA.

Q. Now, there has been a reference, I think you just referenced it, to the SIR guidelines?

A. Yes. 02:22:35

Q. What are those?

MR. O'CONNOR: Objection, Your Honor. Lack of foundation. This is not a medical doctor.

THE COURT: You just have to state the objection. Sustained. You have to lay foundation for that. 02:22:43

BY MR. NORTH: 02:22:45

Q. Are you familiar with the SIR guidelines regarding IVC filters?

A. Yes, I am.

Q. In what context are you familiar with them? 02:22:51

A. It's a reference document that was generated by the Society of Interventional Radiology and it was a consensus document of the literature and the clinical experience of the physician experts who developed this guideline and it was a clinical practice guideline that physicians and industry and 02:23:13 FDA could reference for rates for expected outcomes of events related to vena cava filters.

Q. How did you -- did you, as a part of your work as supervising all of the regulatory affairs efforts at Bard Peripheral Vascular, did you utilize the SIR guidelines in that 02:23:35 work?

A. Yes, we did. We used it frequently in our risk-benefit assessments. FDA frequently asked us to provide copies of the rates of events --

MR. JOHNSON: Objection. That is hearsay Your Honor. 02:23:50

THE COURT: I don't think that's offered for the truth of the matter asserted if it's a question. Overruled.

BY MR. NORTH:

Q. Did you ever have discussions with the FDA concerning SIR guidelines? 02:24:06

A. Yes, I did. 02:24:07

Q. Was it your impression in your discussions with the FDA that they were looking at those guidelines as you were?

A. Yes. They --

MR. O'CONNOR: Objection. Lack of foundation. 02:24:21

THE COURT: Sustained.

BY MR. NORTH:

Q. During this time period, was the company looking at migration reports and comparing the rates of migration that you were seeing with Recovery filters analyzing them against the back drop of the SIR guidelines? 02:24:34

A. Yes.

Q. At any time did the rates of complications with Bard filters -- with the Recovery filter that you were seeing exceed your understanding of what the SIR guidelines were? 02:24:54

A. No.

Q. During this time period and in the investigation of these unfortunate incidents, was the company also looking at the benefit of this filter?

A. Absolutely. That was part of the conversation that we had almost daily is evaluating do the benefits of the filter outweigh the known risks? 02:25:12

Q. And what were the benefits that you believed that this filter brought?

A. The benefits that I believed, and I also heard from 02:25:32

physicians, was that the Recovery filter could be retrieved -- had the ability to be retrieved longer term and many of the patients who were at risk of a pulmonary embolism, that risk could extend beyond the time frame that other competitive filters could be retrieved per IFU. And the Recovery filter had a longer time frame and that was the reason that we believed, and that physicians told us, that the Recovery was advantageous. 02:25:36 02:25:53

Q. Now, you talked about the fact that many of these -- well, let me ask you this: Were you seeing some of the patients that suffered migration of the filter to the heart and that were morbidly obese, were they patients undergoing bariatric surgery? 02:26:17

A. That was one of the common trends that we found in our root cause analysis is that many of them were patients who had bariatric surgery. 02:26:31

Q. So did the company make an effort at that point to understand the use of these devices better in the bariatric patient population?

A. Absolutely. 02:26:46

Q. And did you convene a panel of bariatric surgeons to discuss these issues?

A. Yes, we did.

Q. And did that occur in February of 2005?

A. I don't recall the exact date but it was around that time, 02:26:58

yes.

MR. NORTH: If we could look at Exhibit 5238, please, and if we could go to the second page.

BY MR. NORTH:

Q. Did you attend this meeting, Ms. O'Quinn? 02:27:25

A. Yes, I did.

Q. And where was the meeting? Where did it take place?

A. This meeting was in Chicago.

Q. And was there a PowerPoint prepared to present by Bard to the surgeons? 02:27:42

A. Yes.

Q. And does this appear to be a copy of that PowerPoint?

A. Yes, it does.

MR. NORTH: Your Honor, at this time I would tender Exhibit 5238. 02:27:50

MR. O'CONNOR: Objection, hearsay and lack of foundation. I don't believe this witness prepared this PowerPoint.

THE COURT: Okay. I couldn't hear the last half of what you said. 02:28:02

MR. O'CONNOR: Hearsay and lack of foundation. I apologize. I do not believe this witness prepared this.

THE COURT: Your response on hearsay?

MR. NORTH: Let me ask her a couple more questions.

THE COURT: Yes. 02:28:12

BY MR. NORTH: 02:28:13

Q. Was this PowerPoint prepared in the ordinary course of Bard's business?

A. Yes.

Q. Was a copy of this PowerPoint maintained in the company's files? 02:28:17

A. Yes.

Q. With regard to its investigation regarding this incident?

A. Yes.

Q. And was this prepared at or about the time of the meeting in question? 02:28:25

A. Yes.

MR. NORTH: Your Honor, we would tender it again.

MR. O'CONNOR: Your Honor, as I heard, this was a one-time PowerPoint. This was not a regular activity of this company. Objection, hearsay. 02:28:35

THE COURT: Overruled. 803(6). 5328 can be admitted.

(Exhibit Number 5238 was admitted into evidence.)

COURTROOM DEPUTY: 5238. 02:28:50

THE COURT: Oh. It's 5238. Okay. 5238 is admitted.

BY MR. NORTH:

Q. Let's go to 5238.004, please.

MR. NORTH: And could we display this to the jury, Your Honor? 02:29:10

THE COURT: Yes. 02:29:10

BY MR. NORTH:

Q. Did the company, at this meeting that you attended, explain to the bariatric surgeons the investigative efforts that the company was making with regard to these incidents? 02:29:20

A. Yes, we did.

Q. Let's go to page 24 if we could, 5238.24. Did the company at this meeting explain to the surgeons or give them some information concerning the bench testing that had been performed? 02:29:46

A. Yes.

Q. And let's go to the next page, please.

THE COURT: We're going to break at this point, Mr. North.

Ladies and gentlemen, we will resume at 2:45. 02:29:52

(Jury departs at 2:30.)

MR. O'CONNOR: Your Honor, before the jury returns, can we talk about this slide that's about to be displayed because it's one thing to admit this exhibit, but there are slides in there that have evidentiary flaws. For example, he's going to ask a witness about a table. There is no evidence or foundation who prepared that table, what information was looked at, what data or how it was assembled. He's going to compare different brands of IVC filters in front of this jury without 02:30:24 02:30:42

any foundation through a self-serving slide. 02:30:45

So it's one thing to admit the PowerPoint but there are individual slides here that have very bad -- evidentiary flaws or are objectionable.

THE COURT: Well, if I found that the PowerPoint a business record and admissible under 803(6), what is the evidentiary basis for your wanting to exclude that particular page? I've concluded hearsay isn't an appropriate objection. 02:30:58

MR. O'CONNOR: Because there is an entire lack of foundation for that page. They are going to put conclusions and act like there's been a study and some type of comparison that this company did and the people that did whatever that did and show up in trial. We have no way to cross-examine and explore the truth of that particular table that they are about to show. 02:31:18 02:31:39

THE COURT: Mr. North, can you put up that table?

MR. NORTH: 25.

THE COURT: Is that the table?

MR. NORTH: Yes, Your Honor.

THE COURT: No. I'm asking Mr. O'Connor. 02:31:52

MR. O'CONNOR: That's the table I just saw.

THE COURT: All right, sir.

What's your response, Mr. North?

MR. NORTH: Your Honor, I believe it's a business record. It's a summary of the testing. They have got the 02:32:03

underlying data. The results aren't good for us. I'm not sure what the complaint is. The numbers are very low. I'm just showing it to illustrate that Bard was putting its data out. But -- these tests, they will all be admitted during the course of this trial. Some of them have been admitted by the plaintiffs. They have got the test data. This is just a summary slide and a business record. 02:32:06 02:32:25

MR. O'CONNOR: The problem is, Your Honor, we don't know what these tests are, how they were conducted, whether they were all conducted under similar circumstances, whether they all followed a similar protocol. And the biggest problem of this exhibit is, as I said, they say was prepared by a man named Ganser. And this witness is just being a conduit of whatever this thing says. 02:32:42

MR. NORTH: I'm almost positive they put this exact test report in. 02:33:00

THE COURT: These numbers look familiar.

MR. NORTH: Yes. Where Tulip was the only one down the bottom with Recovery.

THE COURT: I would be interested in whether this is the same numbers that we have seen before. They look like they are the same. Why don't you check that over the break? I want to think about the objection. 02:33:11

MS. MATARAZZO: Your Honor, one other thing I want to mention is I don't know what Mr. North is planning to show but 02:33:21

there's also a summary chart from a medical journal article by Dr. Grassi. That's hearsay. That shouldn't be shown either. There's other flaws with this PowerPoint. I'm not sure what page it was. 02:33:25

THE COURT: Is there hearsay within hearsay, Mr. North? 02:33:40

MR. NORTH: I am not planning on showing anything else after this table. I'm not sure what they are talking about. I would have to see the page.

MS. MATARAZZO: Page 18. 02:33:49

THE COURT: All right. Why don't you all confer about the hearsay within hearsay. If you can't reach agreement, you can raise that within me. My ruling was only that the overall document was a business record.

MR. O'CONNOR: Your Honor, and I would like at this time to remove for that monthly report and that table on the back. If this is a business record, then that is a business record for sure, that put Bard on notice that it was collected on a monthly, on a regular basis. 02:34:00

THE COURT: You're talking about 4327, the last three pages? 02:34:17

MR. O'CONNOR: Yes, sir.

THE COURT: My problem wasn't that that wasn't a business record. My problem was that that was hearsay within hearsay because those last three pages were quoting other 02:34:26

people.

MR. O'CONNOR: But, Your Honor, the evidence shows -- we can show you one every month that it was collected and gathered and maintained in the regular course of their business.

THE COURT: Well, we haven't received any of that evidence. You haven't moved it in separately on that basis. You tried to get it in as part of that record and it was hearsay within hearsay. So let's not take the time now to revisit that while we're keeping the jury out. If you want to raise it later, I'll be happy to hear you. I don't want -- I don't want to talk about a different exhibit during the break.

MR. O'CONNOR: All right. Now, finally, with all of this testimony about bariatric and how concerned they were, yesterday you made us redact a statement by the head of Research and Development and his attitude towards these people that they are now trying to engender sympathy --

THE COURT: I have no idea what you're talking about. Stop arguing and be precise on what you're talking about.

MR. O'CONNOR: Exhibit 64, the core buffet line statement. It was an email about the bariatric patients.

THE COURT: Yes. I did keep that out.

MR. O'CONNOR: Well, under the circumstances, I think we should be allowed to bring that back in.

THE COURT: All right. I don't agree with that so

I'm not going to allow that to happen. If you want to raise a business record basis for those last three pages of that other exhibit that is separate from the one that I've already ruled on, I'll hear you at another time but not now. 02:35:42

As to this chart, I will let you know when I come back in on my ruling. 02:35:57

COURTROOM DEPUTY: And that's 4327 is the last three-page one.

(Recess at 2:36; resumed at 2:46.)

(Jury enters at 2:47.) 02:46:57

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you. Please be seated.

Counsel, on the issue we addressed before the break, I'm not going to exclude the table from the document that has been admitted but you all can confer with the article that's referred to and if you can't reach agreement, let me know. 02:47:52

You may continue, Mr. North.

MR. NORTH: Thank you.

If we could display page 25 of that exhibit, it is 5238. 02:48:05

BY MR. NORTH:

Q. Ms. O'Quinn, did the company, at this bariatric surgery panel, share with attendees the migration-resistance testing that had been done?

A. Yes. 02:48:20

MR. NORTH: And can we also turn to page 27? 02:48:27

BY MR. NORTH:

Q. Did the company share its complication data regarding the Recovery filter with the doctors that attended this panel?

A. Yes. 02:48:41

Q. And what was the purpose generally of having this panel discussion?

A. The purpose of the meeting was to share the adverse event rates and to be transparent with the physicians to get their input to help us with the investigation to be able to determine 02:48:55 if the benefits of the filter outweighed the risk.

Q. Now, did you have a business practice over the course of this time of creating what you called a contact report when you had discussions with the FDA?

A. Yes. 02:49:14

Q. Could you explain to the members of the jury what the purpose of a contact report was?

A. Yes. Whenever I or someone on my team would have a conversation with the FDA, we would record it in a document called a contact report and that contact report is like a memo 02:49:30 that summarizes the discussion with the agency. And we would file that in our regulatory files and make sure that we tracked all of the correspondence or communications with the regulatory agencies.

Q. Did you generally prepare these minutes or these contact 02:49:52

reports very soon after your conversations? 02:49:59
A. Yes, we did. And I certainly speak for myself and the guidelines that we shared with our regulatory team was to document those immediately after the call, sometimes it was generally the same day or within 24 hours. 02:50:14
Q. And were those reports then maintained by the company as a part of your files?
A. Yes. We maintained the correspondence and communication log and we kept all of those.
Q. Let me ask Mr. Russell to pull up 5239, please. 02:50:30
Can you identify this document, please.
A. Yes. This is one of the contact reports that I prepared in January of 2005 based upon my contact with the FDA on the Recovery filter.
MR. NORTH: Your Honor, at this time we would tender 5239. 02:51:11
MR. JOHNSON: Objection, hearsay within hearsay, Your Honor.
THE COURT: All right. Let's talk about that at sidebar, counsel. 02:51:19
Ladies and gentlemen, if you wish to stand, feel free.
(At sidebar 2:51.)
THE COURT: Where is the hearsay within the hearsay?
MR. O'CONNOR: I think it's the last sentence. I 02:51:39

don't have a hard copy of the document. 02:51:40

THE COURT: So it's the statement, "She is very pleased we are keeping her informed of our experience with the Recovery filter"?

MR. O'CONNOR: Yeah. 02:51:58

THE COURT: And actually before that. "Ms. Kennell said she was pleased to hear the rates remained low"?

MR. O'CONNOR: Yes.

THE COURT: Why is that not a recounting --

MR. NORTH: It's a present sense impression under 803(1). 02:52:09 The Ninth Circuit in *United States v. Gill*, the circumstance where officers who were note-takers were allowed to testify regarding observations reported by other officers as present sense impressions.

There's another case from the District of Arizona, 02:52:23 *Liera-Morales*, where substances of phone conversations --

THE COURT: 803 what?

MR. NORTH: 803(1).

THE COURT: Well, but this sentence, the second-to-the-last sentence is not describing Ms. Allen's, 02:52:53 Ms. O'Quinn's impression. It's quoting Ms. Kennell, "Ms. Kennell said." That wouldn't be a present sense impression of Ms. O'Quinn's. It's a quote of what Ms. Kennell said.

MR. NORTH: It's her present sense impression of what 02:53:13

the other party was saying and indicating. 02:53:14

THE COURT: That would overcome all hearsay because we always have a present sense impression of what somebody is saying.

MR. NORTH: I would also suggest that under ***Friedman v. Medjet,*** this is the Central District of California, it's not hearsay in the first instance because it's being recorded to show its effect on the listener and not to be offered for the truth of the matter asserted. 02:53:25

THE COURT: You're not suggesting here that the FDA was happy that Bard was keeping it apprised? 02:53:39

MR. NORTH: That was the impression to her and when punitive damages and our mind set and what we're doing --

THE COURT: Let's do this. I think that issue -- I can't rule on the basis of the cases that you're quoting without reading them. 02:53:54

MR. O'CONNOR: I'm going to need those cases, too.

THE COURT: But with respect to the rest of the document besides those quotations of Ms. Kennell, is there any other hearsay within hearsay? 02:54:12

MR. O'CONNOR: Well, obviously, Your Honor, I think it's an out-of-court statement.

THE COURT: Well, it is but they have laid a business record foundation for the whole document.

MR. O'CONNOR: May I just look at it real quickly, 02:54:22

please. 02:54:24

THE COURT: Yes.

MR. O'CONNOR: I mean, there is so much conclusory things about what they did, the testing they did. This is just unfair to let this in when you even look at, like, down here: 02:54:42
I told Ms. Kennell that I conducted the migration resistance test and they are telling about how they are happy about this. And it's just a very 403 type of document that we can't cross-examine the people that this went to.

And for all we know, this is just something 02:55:02
self-serving that they did understanding that there may be litigation coming down the road. It's one thing to say you're keeping something in the course of business or you're collecting facts. It's another thing where you're collecting self-serving documents. 02:55:21

THE COURT: I understand your objection.

Let me ask you this question, Mr. North. Even if this is a business record, when Ms. Allen is quoting herself saying I told so-and-so something, and she quotes her, that's an out-of-court hearsay statement. The witness can't repeat 02:55:34
what they said out of Court because it's hearsay. Isn't that hearsay within hearsay?

MR. NORTH: I find that hard to see how the author -- she's the author herself and she's recording the business record of a conversation she had. 02:55:55

THE COURT: Yeah. That's true. But any witness on the stand can't put in evidence a letter just by saying, "I wrote it," because it's still hearsay. It's still an out-of-court declaration. 02:55:58

I think what you're arguing is that what she said should be coming in within the business record exception. 02:56:12

MR. NORTH: Exactly. She's the author of the business record. If that was a second layer of hearsay, I'm not sure any business record would be without two layers of hearsay because everybody is recording what they did. 02:56:30

MR. O'CONNOR: If I may be heard on that.

THE COURT: Very briefly.

MR. O'CONNOR: It's all about trustworthiness. When you're collecting facts and your quoting facts, that's why the business hearsay exception is there, because there's some indicia of trustworthiness. But this is a whole different animal. 02:56:41

THE COURT: Well, I understand that point. I don't agree with it. She testified their practice was to record this immediately after the record to keep a record of what the communications were with the FDA. I think that satisfies the business record requirement. But I do think there is hearsay within hearsay where she is quoting what the FDA said to her, and I'll need to read your cases to decide whether that's admissible. 02:56:56 02:57:15

So are you intending to -- 02:57:16

MR. NORTH: I'm not going to display anything.

THE COURT: I'm going to admit the document under the business records exception but subject to your discussions about hearsay within hearsay; and if you can't resolve them, 02:57:26 then I'll be happy to resolve that issue.

MR. O'CONNOR: So is he going to be allowed to publish this?

THE COURT: He said he's not going to.

MR. O'CONNOR: Okay. Thank you. 02:57:39

(End of sidebar discussion.)

THE COURT: Thank you, ladies and gentlemen. Docket 5329 is admitted subject to further discussion by the parties on hearsay within hearsay.

(Exhibit Number 5329 was admitted into evidence.) 02:57:54

BY MR. NORTH:

Q. Ms. O'Quinn, now let's look at Exhibit 5003. Is this another contact report that you prepared?

A. Yes.

Q. And what sort of conversation -- without going into the 02:58:29 details, what sort of conversation? With whom was this conversation?

A. This conversation was with Jenny Liu in the Office of Post Market Surveillance at the FDA.

Q. And when did this conversation occur? 02:58:42

A. That was February 8 of 2005. 02:58:44
Q. And what was the subject of this conversation? Was it the Recovery filter?
A. Yes. And in this we were talking about the -- they are called medical device reports, MDRs, and the -- about -- 02:59:04
MR. O'CONNOR: Excuse me, Your Honor. She's testifying about a document that is not in evidence yet.
THE COURT: Sustained.
MR. NORTH: Your Honor, we would tender 5003. It's the same sort of document. 02:59:19
THE COURT: I understand.
MR. O'CONNOR: Same objection. Hearsay and hearsay.
THE COURT: I'm going to admit it on the same basis I did 5239, meaning -- well --
MR. NORTH: Actually. 02:59:29
THE COURT: Hold on just a minute. You haven't laid the business record foundation of this specific document. You need to do that before I can rule.
MR. NORTH: Thank you, Your Honor.
BY MR. NORTH: 02:59:36
Q. Ms. O'Quinn, was this contact report prepared under the same circumstances as the previous contact report we discussed?
A. Yes.
Q. And was it maintained as a part of the company's files and your files just like the previous report? 02:59:49

A. Yes.
Q. And was it your practice to do so to make these reports like this one at the same time?
A. Yes.
MR. NORTH: Your Honor, I would tender. 02:59:58
THE COURT: All right. Same objection, Mr. O'Connor.
MR. O'CONNOR: And just so we're clear, also on the business record subsection, Your Honor.
THE COURT: Subsection what?
MR. O'CONNOR: Subsection E. I believe I raised this 03:00:13 argument at the sidebar.
THE COURT: You did. I understand the argument. I'm overruling that argument. I'm admitting 5003 under Rule 803(6). However, subject to further discussion about hearsay within hearsay. 03:00:37
(Exhibit Number 5003 was admitted into evidence.)
MR. NORTH: Thank you, Your Honor.
BY MR. NORTH:
Q. Now, did the FDA at some point in this time period pose various questions to Bard regarding the performance of its 03:00:52 filters?
A. Yes.
Q. Let me show you what's been marked 5193. Do you recognize this exhibit?
A. Yes. 03:01:20

Q. And what is this letter? 03:01:21
A. This was a response to the FDA about questions they had on a specific event report.
Q. What was the date of this letter?
A. February -- I believe it's a 5. That's a five, thank you. 03:01:35
Q. Did you maintain this letter in your business records?
A. Yes. We maintained this type of correspondence in our correspondence log.
MR. NORTH: Your Honor, at this time I would tender 5193. 03:02:05
MR. O'CONNOR: This exhibit is subject to the agreement, Your Honor.
THE COURT: Do you agree with that?
MR. NORTH: Yes, Your Honor.
THE COURT: Okay. I'm going to admit Exhibit 5193 subject to the parties' further discussions. 03:02:13
(Exhibit Number 5193 was admitted into evidence.)
BY MR. NORTH:
Q. If we could turn to page 0008.
MR. NORTH: And could I display this, Your Honor? 03:02:24
THE COURT: You may provided it doesn't have one of the topics that you're going to be talking about.
BY MR. NORTH:
Q. As a part of this letter to the FDA, did you provide the agency with updated data concerning the complications that had 03:02:34

been reported with the Recovery filter? 03:02:38
A. Yes.
Q. Let's turn if we could now to the G2 Filter, Ms. O'Quinn. I would like to get you to identify just for the record some exhibits that were actually discussed this morning but to have 03:02:59
these introduced.
If we could first at 5349. Second page. Do you recognize this as the initial submission to the FDA concerning the G2 filter?
A. Yes. 03:03:22
Q. And was this a part of Bard's business records?
A. Yes.
MR. NORTH: Your Honor, at this time I would tender 5349 subject to the agreement.
MR. O'CONNOR: Subject to the agreement, thank you. 03:03:33
THE COURT: All right. Admitted on that basis.
(Exhibit Number 5349 was admitted into evidence.)
BY MR. NORTH:
Q. Now, after this was submitted, was there a meeting with the FDA concerning the G2 submission? 03:03:57
A. Yes.
Q. And do you recall that meeting as being in March of that year, 2005?
A. Yes, I do.
Q. Let me ask you to look at Exhibit 5905. Do you recognize 03:04:07

5905? 03:04:21
A. Yes. That is the agenda that we prepared for the meeting.
Q. And who prepared this agenda?
A. I did.
Q. And was that this part of your business records? 03:04:30
A. Yes.
MR. NORTH: Your Honor, at this time we would tender 5905.
MR. O'CONNOR: May we quickly see the second page of this, Your Honor? 03:04:44
THE COURT: I'm sorry. What did you say?
MR. O'CONNOR: I would like to see the second page.
THE COURT: All right.
MR. O'CONNOR: No objection.
THE COURT: All right. 5905 is admitted. 03:04:51
(Exhibit Number 5905 was admitted into evidence.)
BY MR. NORTH:
Q. Now if we could look at Exhibit 495. Was a PowerPoint presented at the meeting with the FDA in March of 2005?
A. Yes. 03:05:14
Q. And who prepared this PowerPoint?
A. I prepared it with input from multiple people who were attending.
Q. And was this maintained as a part of your business records? 03:05:25

A. Yes.

MR. NORTH: Your Honor, at this time we would tender 495.

MR. O'CONNOR: Objection, hearsay.

THE COURT: I think you need to lay additional foundation, Mr. North. 03:05:38

BY MR. NORTH:

Q. What does this PowerPoint generally contain?

A. The content of the PowerPoint would generally contain the information that was presented to FDA and it would be -- do you want me to describe the specific topics we discussed at this meeting? 03:05:53

Q. And did you prepare this yourself for the meeting?

A. Yes.

Q. And were these topics discussed at the meeting? 03:06:08

A. Yes.

MR. NORTH: Your Honor, I would tender the exhibit.

MR. O'CONNOR: No objection.

THE COURT: 495 is admitted.

(Exhibit Number 495 was admitted into evidence.) 03:06:19

BY MR. NORTH:

Q. After that meeting did the company submit a regular 510(k) for the G2 filter?

A. Yes.

Q. Let me show you what's been marked as Exhibit 5169. Is 03:06:31

that the submission for a 510(k) clearance as a permanent filter for the G2? 03:06:41

A. I would need to see the cover letter but I believe that that is for the permanent indication.

Q. Let's look at the page two and see if that helps you there. 03:06:52

A. Yes.

MR. NORTH: Your Honor, at this time we would tender 5169 subject to the agreement.

COURTROOM DEPUTY: It's already admitted. 03:07:14

THE COURT: We show this already as in evidence.

MR. NORTH: Okay. I'm sorry, Your Honor.

THE WITNESS: I'm sorry, Richard. I think this is for the Recovery, not the G2.

BY MR. NORTH: 03:07:32

Q. Oh. Okay. I apologize. I'm sorry. I got the wrong number there. I have too many documents.

Let's look at 5350 if we could. Is this the submission for the G2 for permanent indication?

A. Yes. 03:08:10

MR. NORTH: Your Honor, at this time we would tender 5350 subject to the agreement.

MR. O'CONNOR: Thank you.

THE COURT: Any objection on that basis?

MR. O'CONNOR: Not -- subject to the agreement. 03:08:22

THE COURT: All right. Admitted on that basis. 03:08:24

(Exhibit Number 5350 was admitted into evidence.)

BY MR. NORTH:

Q. Let's look at 5344 if we could. Following the submission of the 510(k) for the G2 filter as a permanent device, did the FDA come back with questions to the company? 03:08:44

A. Yes, they did.

Q. And could you tell us generally what sorts of questions -- well, let me ask you this: Is this letter from the FDA asking those questions to you? 03:09:05

A. Yes, it is.

Q. And the letter was addressed to Bard Peripheral Vascular in care of you personally; correct?

A. Yes.

Q. And do you recall receiving this letter? 03:09:31

A. Yes, I do.

Q. And did you maintain it in your files?

A. Yes.

MR. NORTH: Your Honor, at this time we would tender 5344. 03:09:38

MR. O'CONNOR: Objection, hearsay.

THE COURT: I think there needs to be additional foundation.

BY MR. NORTH:

Q. Is it typical for the FDA to send you letters as a 03:10:03

follow-up during the 510(k) process asking questions and seeking additional information? 03:10:07

A. Yes, it is.

Q. And is that routinely occurring?

A. Yes. 03:10:17

Q. And when that happens, are those questions generally posed to you by letter form?

A. Yes. Sometimes they could be verbal or email but most of the time they are written and this one was in a letter.

Q. And you had been the original signatory to the 510(k) submission made to the FDA a month or two earlier, correct, for the G2? 03:10:31

A. For the G2, I believe -- I would need to look at the cover letter to verify if it was me or someone on my team. I was involved on the submission but I don't recall, without looking at the letter, if I actually signed it because sometimes members of my team would sign, but I reviewed the submissions. But I believe I submitted but I can't confirm. 03:10:50

Q. As head of the Regulatory Department at Bard Peripheral, it would not be unusual for you to be the person to whom questions by the agency are addressed; correct? 03:11:03

A. Yes, because I had previously informed the FDA that after Mary Edwards, my previous supervisor, departed, that I was the primary contact.

Q. And then is this letter such as this kept as a part of the 03:11:27

company's files regarding the 510(k) process for the device? 03:11:31
A. Yes. It's kept in our correspondence files.
MR. NORTH: Your Honor, at this time I would retender.
MR. O'CONNOR: Objection, hearsay. 03:11:40
THE COURT: Overruled. I think 803(6) has been satisfied.
5344 is admitted.
(Exhibit Number 5344 was admitted into evidence.)
MR. NORTH: If we could publish this to the jury, 03:11:57
Your Honor.
THE COURT: You may.
BY MR. NORTH:
Q. And look at paragraph number one. Did the FDA ask you here for additional information concerning the animal testing, 03:12:08
in vivo testing?
A. Yes.
Q. And did the company provide that data to the FDA?
A. Yes.
Q. Did the FDA eventually clear the G2 filter for permanent 03:12:33
use?
A. Yes.
MR. NORTH: I'm sorry, 5343 admitted.
COURTROOM DEPUTY: 5343?
MR. NORTH: Yes. 03:12:53

COURTROOM DEPUTY: Yes. It's admitted. 03:12:54

BY MR. NORTH:

Q. Are you aware of the fact that when the G2 was introduced to the market in September of 2005 that the Recovery filter stayed on the market for a few additional weeks? 03:13:04

A. Yes.

Q. And explain to the jury why that is.

A. Yes. The reason for it was that many of the cases are scheduled a few days to a couple of weeks in advance and several of the physicians -- when we originally had made the 03:13:21 decision to pull the Recovery filter, the physicians were concerned because they already had cases that were scheduled and they were concerned about disrupting the cases for those patients. So they asked us to keep --

MR. O'CONNOR: Objection, Your Honor, to the hearsay 03:13:39 in this response.

THE COURT: Overruled.

BY MR. NORTH:

Q. Were you involved in submitting a 510(k) for the jugular delivery system for the G2 filter? 03:13:54

A. I'm familiar with it. I supervised the team who submitted it.

Q. If we could look at 5354. And do you recognize that as the special 510(k) submitted regarding the jugular delivery kit? 03:14:21

A. Yes.

MR. NORTH: Your Honor --

Q. Well, would this 510(k) have been maintained as a part of the company's business records -- 03:14:25

A. Yes.

Q. -- within your department? 03:14:32

A. Yes.

MR. NORTH: Your Honor, at this time I would tender 5354 subject to the further review.

MR. O'CONNOR: Subject to the agreement. Thank you. 03:14:42

THE COURT: All right. It's admitted on that basis.

(Exhibit Number 5354 was admitted into evidence.)

BY MR. NORTH:

Q. Let's look at 5361. Were you familiar with the later 510(k) regarding the tight spline issue? 03:15:08

A. Yes.

Q. Is this a copy, 5361, of the 510(k) submitted on that issue?

A. Yes.

Q. And this was maintained in your files? 03:15:18

A. Yes.

MR. NORTH: Your Honor, at this time I would tender 5361.

MR. O'CONNOR: No objection.

THE COURT: Admitted. 03:15:29

(Exhibit Number 5361 was admitted into evidence.) 03:15:30

MR. NORTH: I'm sorry. Has 5353 been admitted?

COURTROOM DEPUTY: Yes.

MR. NORTH: And 5362?

COURTROOM DEPUTY: Yes. 03:15:45

MR. NORTH: Thank you.

BY MR. NORTH:

Q. Let's look at 5324. Clinical Affairs reported to you and within your jurisdiction during this period of time in 2005 and '6; correct? 03:16:09

A. Yes.

Q. And could you identify for the record what 5324 is?

A. That is the investigational device exemption application which is a request to FDA to conduct a clinical study.

Q. And is that what this application, once approved, what led to the EVEREST study? 03:16:30

A. Yes.

Q. And was this prepared, this investigational device exemption, IDE, application prepared by your group under your supervision? 03:16:45

A. Yes.

Q. And was it maintained as a part of your records?

A. Yes.

MR. NORTH: Your Honor, at this time I would tender 5324. 03:16:52

MR. O'CONNOR: No objection. 03:16:56

THE COURT: Admitted.

(Exhibit Number 5324 was admitted into evidence.)

BY MR. NORTH:

Q. Now, let's look at 5323. Did the FDA contact you to 03:17:01
conditionally approve your investigational plan?

A. Yes, they did.

Q. And is this a copy of the letter that you received addressed to you from the FDA regarding the conditional 03:17:33
approval of the application for the IDE?

A. Yes.

Q. And was this letter then maintained as a part of your file regarding the G2 process, clearance process, and the EVEREST study?

A. Yes. 03:17:47

MR. NORTH: Your Honor, at this time I would tender 5323.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit Number 5323 was admitted into evidence.) 03:17:59

BY MR. NORTH:

Q. If we could look at 5325. Is 5325 a letter written by you to the FDA answering various questions concerning the IDE application?

A. Yes. 03:18:34

Q. And you have seen this before? 03:18:35
A. Yes.
Q. And was this a part of your files at the company?
A. Yes.
MR. NORTH: Your Honor, I would tender 5325. 03:18:39
MS. MATARAZZO: No objection subject to the agreement.
MR. O'CONNOR: Oh, thank you.
THE COURT: All right. Admitted on that basis.
(Exhibit Number 5325 was admitted into evidence.) 03:18:49
BY MR. NORTH:
Q. Were there reports of complications in the EVEREST trial?
A. Yes.
Q. Were those reported to the FDA?
A. Yes. 03:19:03
Q. Let's look at 5333. Was the company required to present annual progress reports to the FDA concerning the EVEREST trial?
A. Yes.
Q. And did those reports contain complication -- reports of 03:19:23 complications?
A. Yes.
Q. Is 5333 a copy of an annual progress report provided in February of 2007?
A. Yes. 03:19:38

Q. And were you involved in preparing that report? 03:19:44
A. Yes.
Q. And was that report maintained as a part of your business files?
A. Yes. 03:19:51

MR. NORTH: Your Honor, we would tender 5333.

MR. O'CONNOR: I'm told no objection.

THE COURT: That's good enough for me. We'll admit 5333.

(Exhibit Number 5333 was admitted into evidence.) 03:20:06

BY MR. NORTH:
Q. Ms. O'Quinn, I would like to talk about a different subject right now. The jury has heard quite a bit about the term "caudal migration" throughout the course of this trial. What's your understanding of caudal migration? 03:20:17
A. Cephalad migration is when it moves up and caudal is when it moves down towards the feet.
Q. What's your understanding of the potential severity of caudal migration?
A. Based upon the events that I saw, the caudal migration did not result in any clinical complications and it was generally asymptomatic. 03:20:35
Q. At your time at Bard, were you ever made aware of a patient dying as a result of a caudal migration?
A. No. 03:20:56

Q. When Bard started receiving reports that the G2 was caudally migrating, what did the company do? 03:20:58

A. The same that we generally did which was start a root cause investigation and seek input from experts on what does this mean and what, if any, additional action should we take. 03:21:14

Q. Were you on the team that investigated the reports of caudal migrations?

A. Yes.

Q. The jury has heard a great deal about a document called a DFMEA, Design Failure Modes and Effects Analysis. Can you tell generally -- are you familiar with what that is? 03:21:36

A. Yes.

Q. What is that?

A. That is a tool that device companies use. It wasn't unique to Bard. It's used within the industry as a way of establishing thresholds in order to monitor event rates as they come in and then make decisions based on what we're seeing. 03:21:46

Q. What are DFMEA threshold rates?

A. Generally, those threshold rates are set at a very conservative level especially for a new product. So it will trigger if events occur and trigger those thresholds, meaning they exceed those conservative thresholds that are established, then we would further evaluate what we would need to do. 03:22:13

Q. When setting thresholds, is it preferable for a manufacture to set those high or low? 03:22:39

A. We wanted to set them very low so that we are alerted like a yellow flag or a red flag indicating that we need to further evaluate it. So we want those set low. 03:22:43

Q. Now, for a new device like the G2 was in 2005, how are DFMEA thresholds usually determined? 03:23:00

A. A cross-functional team will evaluate those and set them based upon a conservative estimate.

Q. And what was the basis for the DFMEA threshold rate for G2 migration initially?

A. Initially, it was set based upon the Recovery filter. 03:23:23

Q. What does it mean if a DFMEA threshold rate is exceeded?

A. It means that it is alerted that it has exceeded that threshold and further evaluation needs to occur.

Q. Let's look at Plaintiff's Exhibit 2248 or the Exhibit 2248 which I believe has already been admitted in the case. 03:23:54

THE COURT: Yes, it has.

MR. NORTH: If we could display.

THE COURT: You may.

BY MR. NORTH:

Q. Are you familiar with Ms. Natalie Wong at Bard? Do you remember her? 03:24:21

A. Yes.

Q. And was she involved in the investigation of caudal migrations on the same team as you?

A. Yes. 03:24:30

Q. And do you recall her analysis of the DFMEA in March of 2006? 03:24:31

A. Yes.

Q. Let's look at page 19. That's not the same page but do you recall where she made a finding of unacceptable concerning the quad level G2 filter in -- under this DFMEA? 03:25:03

A. Yes.

Q. And what did that mean to you and the investigative team, that it was unacceptable?

MR. O'CONNOR: Objection. Calls for a hearsay and lack of foundation, Your Honor. I don't think this witness is an engineer and was not involved in this. 03:25:21

THE COURT: Overruled.

BY MR. NORTH:

Q. You may answer. 03:25:32

A. Yes. I was part of the product assessment team that reviewed this and this quad level of three on this tool meant that it was unacceptable for our risk assessment. This wasn't indicating a clinical opinion of unacceptable but it was unacceptable as part of the DFMEA and indicated that we needed to further evaluate the event. 03:25:55

BY MR. NORTH:

Q. And what does the quad level three mean, do you recall?

A. It's at the bottom. Let me read this. At the bottom it says the quad level three requires recommended actions prior to 03:26:18

product release, and those actions could have been an additional review or further investigations. 03:26:22

Q. So in response to that finding that this had reached a quad level three with reports of caudal migration, did the company, in fact, institute further action? 03:26:37

A. Yes.

Q. And what was that further action?

A. We continued to conduct an evaluation of these events and we had a physician come out and review the events with us and I personally reviewed them with him to determine if there was a concern about these events. 03:26:56

Q. Did you meet with a number of experts in the field concerning these reports of caudal migration?

A. Yes.

Q. Did you convene a meeting in Chicago with experts? 03:27:16

A. Yes.

Q. Did you attend that meeting?

A. Yes.

Q. And did you consult with various experts throughout the country in the interventional radiology field about the significance of caudal migration? 03:27:25

A. Yes.

Q. And did you notify the FDA about what the company had found under its DFMEA with regard to caudal migrations?

A. Yes. 03:27:42

Q. Let me show you what's been marked as 5881. Have you seen 5881 before? 03:27:42

A. Yes.

Q. And who is Cynthia Walcott who signed this letter?

A. She was the person in our Quality Department that was responsible for the evaluation of these events called MDRs, medical device reports. 03:28:30

Q. When the Quality Department was corresponding directly to the FDA in response to various inquiries, were those responses generally reviewed by you and your department? 03:28:51

A. Not all of them but many of the correspondences were reviewed by my department, if it was anything other than just a routine clarification or simple information.

Q. Would a letter of this nature be reviewed do you believe?

A. Yes. 03:29:10

Q. And why is that?

A. It was because it was requesting specific information about the event that was more detailed other than just a clarification or more clerical type clarification to the report. 03:29:27

Q. Was this maintained in the company's files as a business record.

A. Yes. We maintained those in the MDR report files.

MR. NORTH: Your Honor, at this time I would tender 5881. 03:29:39

MR. O'CONNOR: No objection. 03:29:49

THE COURT: Admitted.

(Exhibit Number 5881 was admitted into evidence.)

MR. NORTH: Could we display, Your Honor?

THE COURT: Yes. 03:29:54

BY MR. NORTH:

Q. Let's look on the second page at number four. In this letter, did the company notify the FDA that in its analysis of caudal migration in the DFMEA as it was originally constituted, the caudal migration rate was found to be an issue? 03:30:18

A. Yes.

Q. And what did the company tell the FDA that it had done in response to this finding?

A. That we had reassessed as part of our evaluation and we had deemed that it remains below the clinical risk threshold 03:30:41 and that it remains acceptable.

Q. Well, why did you change the threshold? What justified changing the threshold for caudal migrations?

MR. O'CONNOR: Objection.

THE WITNESS: Lack of foundation, Your Honor. 03:31:03

THE COURT: Sustained. I think you need to lay foundation.

BY MR. NORTH:

Q. Were you involved on the investigative team as a part of the process of changing the threshold definition for caudal 03:31:10

migrations? 03:31:14
A. Yes.
Q. And was that something the team did together?
A. Yes.
Q. Can you tell us now what the basis of the team's decision 03:31:22
was regarding the threshold for caudal migrations under the DFMEA?
A. Yes. The --
MR. O'CONNOR: Still objection, lack of foundation in terms of what method was used. 03:31:36
THE COURT: Overruled.
BY MR. NORTH:
Q. You may answer.
A. Okay. It was based upon feedback from the physicians that said that if the event was asymptomatic, it shouldn't be part 03:31:48
of the same threshold rate that was originally established for Recovery because that was based upon all migrations, including the cephalad, towards the heart, and that there had been no indication that the caudal migrations had resulted in any clinical events. 03:32:15
Q. Did the FDA protest or question the decision to reassess that threshold given the difference between caudal and cephalad migrations?
MR. JOHNSON: Objection. Hearsay.
THE COURT: Depends on what the answer is. 03:32:36

BY MR. NORTH: 03:32:38

Q. Just -- let me rephrase if I could.

THE COURT: All right.

BY MR. NORTH:

Q. Did the FDA ever indicate to you any concern about the change in the threshold because of the difference between caudal and cephalad migrations? 03:32:42

MR. O'CONNOR: Objection, hearsay.

THE COURT: It's the same question. It depends on the answer. If she says no, it's not hearsay. If says yes, it's hearsay. 03:32:57

MR. NORTH: Well, I wouldn't ask her the follow-up question which is what did they say.

THE COURT: Overruled.

THE WITNESS: I can answer it? 03:33:13

BY MR. NORTH:

Q. Yes, you may answer. I'm sorry.

A. No, they did not.

Q. If we could look at Exhibit 5879, please. Is this another letter sent to the FDA? If we could look at the second page here, too. Is this a follow-up letter sent by Ms. Walcott to the FDA about the same topic? 03:33:40

A. Yes. It was about the DFMEA.

Q. And was this, again, sent to the FDA after a review by you and/or your department? 03:34:02

A. Yes.
Q. And was this maintained in the regular business records of the company?
A. Yes.
MR. NORTH: Your Honor, at this time we would tender 5879. 03:34:09
MR. O'CONNOR: I'm looking at it Your Honor. It's hearsay within hearsay.
THE COURT: Where are you looking?
MR. O'CONNOR: Page two, for example, the table and the lack of foundation for whoever made that table. 03:34:26
THE COURT: Overruled. I think it's a business record. 5879 is admitted.
(Exhibit Number 5879 was admitted into evidence.)
MR. NORTH: May we publish, Your Honor? 03:34:53
THE COURT: Yes.
BY MR. NORTH:
Q. If we could look at the first page at the bottom of the page, the last two paragraphs. Did Bard here provide the FDA with further explanation regarding the DFMEA and the adjustment to the threshold? 03:35:15
A. Yes.
Q. And then if we could look at 5880 and could we look at the second page. Is this another follow-up from Ms. Walcott?
A. Yes. 03:36:16

Q. And was this, again, prepared with input from you or your department? 03:36:18

A. Yes.

Q. And was this maintained as a business record?

A. Yes. 03:36:25

Q. And was this, again, addressing caudal migrations?

A. Yes.

MR. NORTH: Your Honor, at this time we would tender 5880.

MR. O'CONNOR: No objection. 03:36:38

THE COURT: Admitted.

(Exhibit Number 5880 was admitted into evidence.)

MR. NORTH: Is 5539 admitted?

COURTROOM DEPUTY: No.

MR. NORTH: Could we display 5539? 03:36:59

BY MR. NORTH:

Q. Was a formal Failure Investigation Report prepared regarding the investigation into caudal migration?

A. Yes.

Q. And were you a signatory to that report? 03:37:17

A. Yes.

Q. Is this a copy of that report?

A. Yes.

Q. Was it maintained in the company's business files?

A. Yes. 03:37:26

Q. And was it prepared with direct input from you? 03:37:27

A. Yes.

MR. NORTH: Your Honor, at this time I would tender 5539.

MR. O'CONNOR: May I see the second page? 03:37:36

THE COURT: Please.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit Number 5539 was admitted into evidence.)

BY MR. NORTH: 03:38:00

Q. During the entire time there, did the company -- your entire time there, did Bard continue to track adverse event reports with the G2 filter?

A. Yes.

Q. Including all reports of caudal migration? 03:38:13

A. Yes.

Q. Did the company ever, as far as your involvement or knowledge, reach a determination that the risks of the device were outweighing the benefits?

A. No. 03:38:25

Q. And after the adjustment was made to the threshold based upon the difference between the severity of cephalad migrations versus caudal migrations, was there ever a time when the rate of caudal migrations triggered a finding of unacceptable?

A. No. 03:38:45

MR. O'CONNOR: Objection. Lack of foundation. 03:38:46

THE COURT: Overruled.

BY MR. NORTH:

Q. Ms. Allen, you were there with Bard Peripheral Vascular when these reports came in regarding people dying, perhaps 03:39:10 associated with the migration of the Recovery filter; correct?

A. Yes.

Q. And was that difficult for you?

A. It was. It was very difficult and we took those very seriously. We were constantly evaluating these rates because 03:39:26 we cared tremendously about the patients that our products served.

Q. Even though you were receiving these reports of a small number of incidents of migrations and death with the Recovery filter, did you and your colleagues, to your knowledge, reach a 03:39:53 conclusion that the risks of the Recovery filter outweighed its benefits?

A. No.

Q. Did you continue to believe that the Recovery filter provided a valuable therapeutic tool to doctors? 03:40:08

A. Yes, I did, and one of my family members received the product.

MR. O'CONNOR: Object. Irrelevant, Your Honor.

THE COURT: Overruled.

\\\

BY MR. NORTH: 03:40:24

Q. I'm sorry. Could you repeat what you just said?

THE COURT: She said the answer.

MR. NORTH: Okay.

BY MR. NORTH: 03:40:33

Q. During your entire time with the G2 filter working with that, did you ever find a problem or see a problem that made you believe that the risks of the product outweighed its benefits?

A. No. 03:40:43

Q. And during your entire time when you were working with the G2 filter, did you believe it provided a valuable therapeutic benefit to patients?

A. Yes, I did.

Q. Thank you. 03:40:54

MR. NORTH: That's all the questions I have.

THE COURT: Cross-examination?

CROSS - EXAMINATION

BY MR. O'CONNOR:

Q. Good afternoon. It's Mrs. O'Quinn? 03:41:28

A. Yes. My name, when I was at Bard, was Allen and I have gotten married and -- or actually divorced and changed my name back to my maiden name of O'Quinn.

Q. Okay. You're O'Quinn, I'm O'Connor. Mark O'Connor. I've never met you before but nice to meet you today. 03:41:46

So Ms. O'Quinn, let me just start out, Bard, as a manufacturer of devices such as filters, has a duty of safety even after the filter's released to the market; correct? 03:41:48

A. Yes.

Q. And Bard can, on its own, without any prodding from the FDA, take steps to warn doctors, alert doctors or even recall the product. True? 03:42:04

A. Yes.

Q. And Bard doesn't need the FDA to tell it to do something that a company acting in the interest of patient safety should do. Is that fair? 03:42:23

A. We're not required to but we generally do inform the FDA.

Q. I understand you do. But Bard should always put patient safety first; correct?

A. Of course. 03:42:37

Q. Now, we talked about a lot but let me ask you a question about the Recovery 510(k) submission that you talked about. If we could look at 5169 and go to page 19. Well, let me just put that up real quick.

MR. O'CONNOR: Is this it? Go to the first page, please. Okay, thank you. 03:43:25

BY MR. O'CONNOR:

Q. Yes, this is Exhibit 5169 that you talked about earlier; is that right?

A. Yes. 03:43:47

Q. And this is something that I think you said you were involved in; correct? 03:43:48

A. I was not involved in preparing it but I became familiar with it because this was about the time I started at the company. 03:44:00

Q. I see. So anybody that prepared this document, the 510(k) submission, has an obligation to be truthful and accurate; correct?

A. Yes, correct.

Q. I mean, due diligence is very important; right? 03:44:11

A. Of course, yes.

Q. And any information that is put in this document should be verified to be accurate to be truthful; correct?

A. Correct.

Q. All right. 03:44:20

MR. O'CONNOR: Let's go to page 19 if we could. I have a different copy. Go to page 29. No, excuse me. I'm sorry. It should be at page 29, please. I think it would be our page 29.

BY MR. O'CONNOR: 03:45:08

Q. Well, let me just ask you a question, Ms. O'Quinn. There's a statement in the 510(k) submission that you talked about on direct examination that says Dr. Asch's data relative to complications during filter placement recurring pulmonary embolism death, filter migration, et cetera, provided clinical 03:45:24

data to support a determination of substantial equivalence as a permanent filter. Do you recall seeing that statement? 03:45:29

A. Yes.

Q. Do you know who Dr. Asch is?

A. I am familiar with his name. I have not met him. 03:45:39

Q. And if Dr. Asch testified that he advised Bard and was always -- it was always his intention that his study not be used to establish substantial equivalence, then the statement in the 510(k) would be inaccurate; true?

A. I never heard that from Dr. Asch. 03:45:58

Q. But if you assumed that that is Dr. Asch's testimony, would you agree that the statement I just read to you would be inaccurate?

A. Not if they were unaware of that at the time that they signed it. 03:46:10

Q. Well, if they were talking to Dr. Asch and understood the purpose of Dr. Asch's study, that's something they should do; correct? From Bard.

A. From Bard?

Q. Yes. 03:46:22

A. To my knowledge, Bard was never aware.

Q. Well, Bard -- just so you and I are on the same page, when Bard did this 510(k) submission, whoever prepared the paperwork in this had to be truthful and accurate; correct?

A. Yes, correct. 03:46:35

Q. And verify any statements it said about any study or the purpose of any study? 03:46:36

A. The data needed to be accurate.

Q. Now, you talked about the Miami death and when was that death? 03:47:03

A. I don't recall the exact date. I'm familiar with the event but dates, I couldn't give you a date.

Q. But that wasn't the only death that Bard became aware of that was associated with the Recovery filter, was it?

A. No. 03:47:17

Q. There were other deaths?

A. Yes.

Q. Do you know how many?

A. I don't recall the specific numbers but we documented those frequently in our evaluations. 03:47:23

Q. Do you know that there were more than nine as many or how many there were?

A. There were always less than one percent.

Q. I'm asking if you know how many there were.

A. The absolute numbers I don't recall, the actual numbers. 03:47:38 But I documented them frequently.

Q. All right. But the one that got investigated was the Miami death; right?

A. All of the events were investigated.

Q. All right. Well, you talked about the Miami death. Do 03:47:52

you recall that testimony? 03:47:55
A. Yes.
Q. And you told us that there were certain things that were done after the death, the Miami death, concluding a Dear Doctor letter which is Exhibit 5001? 03:48:07
MR. O'CONNOR: Can we see that?
BY MR. O'CONNOR:
Q. Now, is it your testimony that this was done in response to the Miami death?
A. I don't recall if it was that specific event that was one of the -- one of the events that contributed to this. 03:48:23
Q. But do you agree that 5001, Exhibit 5001, mentions nothing about the death in Miami?
A. No. Generally, we wouldn't include information about specific events in patients. 03:48:46
Q. You agree there's nothing mentioned about the death in this document?
A. The document talks about the risks of migration and fracture --
Q. My question is a little different, ma'am. Do you agree the Miami death, individual deaths that Bard investigated, are not mentioned anywhere in this document? Do you agree with that? 03:49:00
A. The Miami death, no, it is not.
Q. Pardon me? 03:49:11

A. No, that event is not mentioned. 03:49:12
Q. And you I think told us that this was sent oh to doctors to help them and let them know what Bard had found in the investigation?
A. Yes. 03:49:27
Q. And that you wanted them to make sure that they reported adverse events?
A. Yes.
Q. I couldn't find a date on this letter. Can you point me to what date this letter went out? 03:49:42
A. I don't recall the date but I could look at the records of the correspondence log and -- because we tracked that.
Q. But you didn't bring down to report here today when this letter was sent or a list of all of the doctors that it was sent to. Is that true? 03:50:00
A. I am no longer an employee of Bard but Bard has those records.
Q. Did you see those records before you came here to testify today?
A. Today, no. 03:50:09
Q. But there's nothing in this letter that tells doctors that if they have a patient with an implanted Recovery, they should bring the patient back and take steps to monitor that patient; true?
A. The intent of the letter was to inform physicians about 03:50:27

the risks so they could make the choices of how to follow -- 03:50:29
Q. Nothing in the letter from Bard says that physicians should get their patients back in and look at the filter either radiographically or remove the filter. Is that fair?
A. We didn't make that specific recommendation. 03:50:43
Q. And as a matter of fact, after the Miami death, the Recovery filter continued to be on the market; true?
A. The Recovery filter, yes.
Q. And so Bard, knowing there were other deaths, knowing there were migrations, and knowing that there were other 03:51:07
complications, even in the face of the Miami death, continued to sell it; right?
A. We did. We continued to evaluate the rates as part of our investigations.
Q. Okay. My question is a little bit different, though. 03:51:23
Setting aside what you've told us you've done, one thing we do know is that in view of the Recovery deaths that Bard became aware of, in view of the death in Miami that the attorney for Bard and you talked about extensively, in view of the number of
complications, migration-related injuries, that Bard was aware 03:51:47
of, Bard continued to sell the Recovery, yes or no?
A. Yes.
Q. And Bard took other steps in following the Miami death, didn't it? You talked about investigation and I think you told us that there was a lot of concern about the bariatric patient 03:52:16

and I would assume people like you at least in Bard were concerned about the other deaths that you had learned about; right? 03:52:22

A. We were concerned about all of them.

Q. And you told us that it was bariatric patients who were largely the patients that the concern was about; right? 03:52:34

A. We were concerned about all patients and we found that in the bariatric patients there was a higher rate but we were concerned about all patients.

Q. And you told us how you felt but certainly different people have different feelings, don't they? And if somebody in a different department was sending an email that mocked bariatric patients or said things that were jokes and not taken this situation seriously, you would not like that, would you? 03:52:56

MR. NORTH: Objection, 402, 403. 03:53:20

THE COURT: Sustained.

MR. O'CONNOR: May I see Exhibit 106, please.

BY MR. O'CONNOR:

Q. Ms. O'Quinn, do you recognize Exhibit 106?

A. No, I don't. 03:54:02

Q. Were you aware that Bard had requested a crisis communication plan following the Recovery deaths?

A. No. I was not aware of it. The first time I heard was when someone presented it to me during a deposition.

Q. Pardon me? 03:54:20

A. I said the first time was during a deposition. 03:54:21

MR. O'CONNOR: Your Honor, I would move to admit this Exhibit 106 into evidence.

MR. NORTH: Objection, Your Honor. 402, 403, she has no personal knowledge. 602. 03:54:38

THE COURT: Hold just a minute. Are there more pages than this?

MR. O'CONNOR: There's several pages, yes.

MR. NORTH: And 802, Your Honor.

THE COURT: Sustained on hearsay grounds. 03:54:55

BY MR. O'CONNOR:

Q. Well, you learned at your depositions that this was a document that was prepared by a consultant that was retained by Bard; correct?

A. I never, when I worked at Bard, heard about a crisis communication plan. 03:55:07

Q. Were you given a step-by-step guide on how to communicate with people and doctors outside of Bard about the crisis that you had learned about?

A. No. 03:55:22

Q. Did you have interaction personally with doctors that were treating patients and putting filters in?

A. Yes.

Q. Were you contacting and selling filters to them and promoting filters? 03:55:33

A. No.
Q. Now, you talked to us about the DFMEAs and I think you mentioned that there were guidelines that were referred to; correct?
A. Yes. 03:55:58
Q. And I think you mentioned there were SIR guidelines.
A. Yes.
Q. And were you aware that the author of those guidelines was Clement Grassi?
A. Yes. 03:56:11
Q. You know that name.
A. I know the name, yes.
Q. And are you ware that Dr. Grassi has testified that the SIR guidelines were not intended to be an instruction manual for manufacturers? Did you know he said that, he testified to 03:56:30
that?
A. No.
Q. Were you aware that there has been testimony that the SIR guidelines were not intended to be acceptable thresholds or thresholds that are acceptable for complication rates? 03:56:49
A. I'm not aware of any testimony but I'm aware of the interpretation of how those guidelines should be used.
Q. And you know that they should not be used as any type of threshold of what is acceptable or not; correct?
A. They aren't intended to be the absolute threshold but that 03:57:09

was only one of the points of information that we considered. 03:57:12
Q. I understand, Ms. O'Quinn, but just so I can get an answer to my question, you do agree and you did understand that the SIR guidelines were never intended to provide any type of threshold that was acceptable for complication rates? Do you 03:57:29
understand that, yes or no, please.
A. It depends on some of the nuances. Yes, not as an absolute threshold, yes.
Q. Thank you.
Now, I take it you personally were not involved in 03:57:48
any testing yourself. Is that fair?
A. That's correct.
Q. And you didn't design any of the bench testing that was done, did you?
A. I did not. I was aware of it. 03:57:57
Q. But you're not an engineer?
A. No, I'm not an engineer.
Q. There were engineers at Bard that did the bench testing and actually designed the test; correct?
A. Yes. 03:58:08
Q. And you weren't doing any type of -- and weren't involved in any type of engineering calculations for things that established migration resistance or fracture resistance, were you?
A. No. 03:58:20

Q. And I take it you wouldn't -- with your background and education, that's something that you wouldn't even begin to try to explain. Fair? 03:58:21

A. I had to explain it in the submissions to the FDA but I am not an expert in the testing, no. 03:58:35

Q. Thank you.

MR. O'CONNOR: I'm sorry, Your Honor. May I ask a question?

May we see Exhibit 546, please.

Your Honor, may I publish this to the jury, please. 03:59:41

THE COURT: Yes. It's in evidence.

BY MR. O'CONNOR:

Q. Ms. O'Quinn, have you ever seen this email before?

A. My name is not on this email.

Q. Did you happen to see it at any time? 04:00:06

A. I don't recall this specific email.

Q. Well, the email is from an individual named John Lehmann. Did you know who he was?

A. Yes. I am familiar with his name.

Q. All right. And this email is dated April 15, 2004. Do you see that? 04:00:23

A. Yes.

Q. And why don't you take a moment and look at it and let's just go to the paragraph where it says "Overall simple message needs to be" right at the top there. Overall and start down 04:00:49

and let's go down to the paragraph that begins with "Comparison." 04:00:53

This is an email that is talking about how the company should communicate when dealing with issues that were going on in 2004. Does that make sense to you? 04:01:12

A. No, it doesn't.

Q. Well, here, as you can see, Mr. Lehmann advised that overall, the simple message needs to be -- and he went down and talked about what a properly placed filter can resist force of fair amount of blood clot. 04:01:29

Do you see where I'm reading?

A. Yes.

Q. And he says that -- he goes on to say there are two facts that need to be communicated in number three.

And then where he has bottom line, do you see that? 04:01:49

Do you see where bottom line is?

A. Yes.

Q. Mr. Lehmann advised Bard that the bottom line is good filter, severe case, bad outcome, deep regret. This is a simple story we should repeat again and again. 04:02:06

Now, did I read that correctly?

A. Yes.

Q. And when you sent out the Dear Colleague letter and you sent out the Dear Doctor letter, there was no mention of the death in Miami. Fair? 04:02:19

A. Yes, but I've never seen this. 04:02:25
Q. I understand. But what those letters did was to explain to physicians that they needed to take -- well, let me back up.
The Dear Colleague letter that you talked about earlier was sent around the same time in 2004; correct? 04:02:42
A. I don't recall the specific dates but I believe that's correct.
Q. It was after the Miami death?
A. Yes.
Q. Thank you. 04:02:52
Now, you talked -- thank you. You talked about the EVEREST test and your involvement. The EVEREST study, were you involved in that?
A. Yes.
Q. And you were involved in that -- were you involved in that study pretty intimately? 04:03:18
A. Yes.
Q. Were you keeping yourself apprised of the study as it was going on?
A. Yes. 04:03:28
Q. And did you know Dr. Kandarpa?
A. I believe that he was the medical monitor that we used for our Clinical Events Committee which was the Safety Review Committee.
Q. And what you were receiving at Bard were regular medical 04:03:43

monitor adjudication meeting minutes correct? 04:03:49
A. Yes, correct.
Q. And you were maintaining those just like the other business documents, fair?
A. Yes. 04:03:56
Q. And they were kept in the ordinary course of Bard's business; correct?
A. Yes.
Q. And it was important that you were having regular meetings with the people involved in the study so that you could follow 04:04:06 the progress of the study; correct?
A. Yes.
Q. And whether you were at a meeting or not, you would keep yourself apprised of what happened at any meeting; true?
A. Yes. 04:04:18
Q. That was important to you?
A. Of course, yes.
Q. It was an important study because the purpose of the study was to determine whether the G2 could be removed or retrievable; right? 04:04:30
A. That was one of the purposes of the study, yes.
Q. At that time -- and the study was going on even in 2006; right?
A. Yes.
Q. And the G2 had already been and on the market; correct? 04:04:45

A. As a permanent filter, yes. 04:04:49
Q. And it was being sold as a permanent filter; correct?
A. Yes.
Q. And it was being implanted in patients; right?
A. Yes. 04:04:55
Q. And after the G2 was released as a permanent filter, you people at Bard, the folks at Bard started learning that the G2 filter was caudally migrating; correct?
A. Yes.
Q. And the folks at Bard were finding out that the G2 filter 04:05:11 was tilting; right?
A. Yes.
Q. And that it was perforating through vena cavas; correct?
A. Yes.
Q. You were receiving reports that the G2 was causing 04:05:20 injuries to patients; right?
A. Yes.
Q. And there was a concern because the G2, unlike other filters that came out from Bard, was doing caudal migration, it was perforating, it was breaking and it was causing injury to 04:05:37 organs and injuries to patients; correct?
A. But those are complications that are common to all filters.
Q. But that is -- you were concerned about your Bard filter and you knew that was going on with the G2 filter; correct? 04:05:48

A. Yes. We were concerned with our filter. 04:05:52
Q. And you talked about earlier that caudal migration test that Natalie Wong did, do you remember that?
A. Yes.
Q. And that even after the findings there where Natalie Wong found an unacceptable risk, caudal migration -- you recall seeing that; right? 04:06:03
A. But, again, the unacceptable was a term that was used in the DFMEA. That didn't imply the clinical unacceptable.
Q. I'm just referring to what was stated in the document. 04:06:20
A. Yes.
Q. The G2 continued to be sold by Bard; right?
A. Yes.

MR. O'CONNOR: Can we see Exhibit 6046, please.

BY MR. O'CONNOR: 04:06:49
Q. This is the type of document that you were receiving on a regular basis from the EVEREST study; is that right?
A. Yes.
Q. And this is the type of document that -- this is a document that you were maintaining in your files in the regular course of Bard's business; correct? 04:07:04
A. Yes.

MR. O'CONNOR: Move for admission of 6046, please.

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted. 04:07:14

(Exhibit Number 6046 was admitted into evidence.) 04:07:15

BY MR. O'CONNOR:

Q. And you remember who Dr. Kandarpa was; correct?

A. Yes.

Q. And did you learn that Dr. Kandarpa had concerns about the G2 filter? 04:07:23

A. No.

Q. All right. Let's go to the second page and let's look at -- I think you told us there were 100 patients enrolled; is that right? 04:07:43

A. That was the enrollment target. I don't know how many had been enrolled as of that point.

Q. Well, as of August 27, 2006, it says there were 100 patients enrolled. Do you see that?

A. Yes. 04:07:58

Q. Thank you.

Okay. Let's go down to the next paragraph that starts out "As part of the clinical update"?

MR. O'CONNOR: Oh. May I publish to the jury, Your Honor? 04:08:14

THE COURT: You may.

BY MR. O'CONNOR:

Q. And into the study, as you can see, there were findings that there were many tilts in the study with site 07 reporting the most. Do you see where I read? 04:08:37

A. Yes.
Q. And then it talks about a patient who had significant device issues. Do you see that?
A. Yes.
Q. And then it goes on to say Dr. Kandarpa expressed concern about the number of reported tilts hitting approximately 20 percent and thought that Bard may want to closely evaluate.
Do you see where I read that, Ms. O'Quinn?
A. Yes.
Q. Now, Bard needed this study to get the retrievability indication for the G2; right?
A. Yes.
Q. And Bard had brought in people to conduct the study, including doctors like -- well, including Dr. Kandarpa who was actually the medical monitor; correct?
A. He was the medical monitor. I don't know if he had ever placed a filter or not.
Q. Well, what you can see is that he had concerns as of August of 2006 about the G2. Do you see that?
A. About the tilting, yes.
Q. Okay. And then go down to Action, please.
It said Dr. Kandarpa recommended examining the literature to see how this rate compares to that published for other devices.
Do you see where I read?

A. Yes. 04:10:17
Q. And then if you go below to the next paragraph and if you look, Dr. Kandarpa was still talking about concerns.
MR. O'CONNOR: Can you highlight the sentence with Dr. Kandarpa? Thank you. 04:10:34
BY MR. O'CONNOR:
Q. Dr. Kandarpa wanted to know if we were concerned that almost 50 percent of patients have a reported AE/SAE.
Now, Ms. O'Quinn, is it fair to say that AE means adverse event? 04:11:00
A. Yes.
Q. And SAE means?
A. Serious adverse event.
Q. Serious adverse event.
A. But these were not related to the device. These were all events. 04:11:08
Q. But Dr. Kandarpa was certainly concerned about what he saw about filter tilting and about the adverse events that were occurring to the patients in the study. You agree with that?
A. It was because of the conservative way we were reporting the way of events that things that were unrelated to the device. 04:11:22
Q. Do you have any reason to dispute that Dr. Kandarpa was concerned and wanted to know if Bard was concerned?
A. Yes. Absolutely. And we were. We looked -- you know, we 04:11:33

always took feedback seriously. 04:11:37

Q. But even after August of -- August 28 of 2006, Bard went on and got the retrievability indication; correct?

A. After I left the company, yes.

Q. And did not change the designs of the G2; correct? 04:11:52

A. I don't know. I was not with the company at that time.

Q. But that was your understanding, that the G2 as it existed would eventually hopefully get a retrievable indication. Fair?

A. Yes.

Q. But it would be marketed and promoted as a permanent filter with the option to be retrieved? 04:12:09

A. Yes.

Q. All right. And during your remaining time at Bard, you continued to learn that that filter, the G2 filter that was being implanted in patients, was tilting, was perforating, was fracturing, and was migrating; correct? 04:12:25

A. Yes, and we evaluated all of those.

Q. But never did Bard take any steps to tell their doctors to get their patients back into their offices and consider either monitoring or removing the filter. Is that true? 04:12:47

A. We informed the physicians of the risks but didn't make the specific recommendation for any kind of imaging follow-up. We left that to the discretion of the physician based upon the risk.

Q. You never advised doctors that based upon what you know, 04:13:00

they should bring the patients back and have them monitored. Is that fair? 04:13:05

A. Yes.

Q. And Bard never told doctors that they should consider getting all their patients back and seeing if there is any type of complication that may result in a domino effect of other complications; true? 04:13:13

A. We didn't make -- it's typical not to make recommendations about follow-up because we leave that to the physician's discretion because we can't practice medicine. 04:13:34

Q. My question is this: Nothing prevented you from communicating adverse events, problems with your filter to doctors; correct? There was nothing that prevented you from doing that. Fair?

A. It depends on the type of information. 04:13:50

Q. Is it fair to say, yes or no, Ms. O'Quinn, that Bard never contacted doctors, never sent a Dear Doctor letter, never sent a Dear Colleague letter advising doctors that they continued to receive reports of the G2 migrating, tilting, fracturing, and perforating and that the doctors should bring their patients back to their office? Is that fair? 04:14:11

A. We did disclose those risks but we didn't say specifically that the patient should return.

Q. All right. And never in any communication to the doctors did you ever say that what we are finding is that there is a 04:14:29

relationship between migration, tilt, and that each failure mode that we are aware of may lead to another failure mode? You never advised doctors of that; true? 04:14:32

A. I am not aware of what that cascade would look like so we didn't address it. 04:14:49

Q. Fair to say during the time that you were there, you're unaware of any warning or communication to doctors about a cascade of failures. True?

A. Yes.

MR. O'CONNOR: May we have 704, Your Honor. 04:15:26

Your Honor, I would move to admit Exhibit 704 into evidence based upon the foundation I laid before. If you could just -- if we could just look at this one moment. I'm ready to wrap it up.

THE COURT: I don't know what foundation you're referring to, Mr. O'Connor. 04:16:10

MR. O'CONNOR: This is, again, the medical monitor adjudication and it's dated August 28, 2006.

THE COURT: I don't think you asked her about this document. 04:16:20

MR. O'CONNOR: Well, this is similar to the last document we looked at.

Q. This is one that was maintained in Bard's ordinary course of business; correct?

A. This is the -- 04:16:32

MR. NORTH: Objection, Your Honor. Can we approach? 04:16:33

THE COURT: Counsel, we are at 4:17. We have three minutes left. I don't want to keep the jury waiting while we discuss this but I also don't want to make the witness come back Monday morning. We're close to being done. 04:16:46

How much more time?

MR. O'CONNOR: I can wrap this up in just two minutes.

THE COURT: And how much redirect?

MR. NORTH: I have no redirect. It's not a Bard 04:16:54
document. It's from a third-party vendor.

THE COURT: See if you can lay the foundation. It needs to be laid with respect to this document.

BY MR. O'CONNOR:

Q. You testified that Bard received these reports on a 04:17:07
regular basis and maintained them in the ordinary course of business; correct?

A. Yes, but this document is an excerpt. I don't know if this is a finished document. I can't tell, based on what I'm seeing here, if I received this document. It looks like an 04:17:21
excerpt.

Q. Well, it's a document that has been produced in this case.

MR. O'CONNOR: I would ask that 704 be admitted into evidence.

MR. NORTH: Objection. 901. It's not a Bard 04:17:40

document. 602 and 803 -- 802. 04:17:42

THE COURT: Sustained as hearsay. Foundation has not been laid for this document.

MR. O'CONNOR: Well, the foundation is there. This is a document that they maintained. May we approach? 04:17:53

THE COURT: You have not established that with this witness.

BY MR. O'CONNOR:

Q. This says Bard EVEREST just like the last one we looked at; correct? 04:18:07

A. Yes. But my name is not on it so I don't know if we actually received it.

Q. Your name wasn't on the last one. Your name was on them sometimes but not always if you weren't at the meetings; true?

A. This types of documents -- yes. 04:18:17

Q. And even if you weren't at the meeting, you would still review each report; correct?

A. I didn't personally review them but my team did, yes.

Q. And they would maintain them in a file at Bard in the regular course of business; correct? 04:18:31

A. These types of -- yes.

Q. And this document is the type of document that was being maintained by Bard; fair?

A. It's the type of document, yes.

MR. O'CONNOR: All right. Move for its admission, 04:18:43

Your Honor. 04:18:45

MR. NORTH: Your Honor, it does not bear a Bard Bates number. It did not come from Bard's files. 901, 802.

THE COURT: Are there any other questions that you're going to ask if I admit it? 04:18:58

MR. O'CONNOR: Yes.

THE COURT: Your patience, ladies and gentlemen.

Come to sidebar.

(At sidebar 4:19.)

THE COURT: Hold on. Let me tell you my problem. 04:19:27

803(6) is record-specific. Each of the elements have to be established with respect to the record by a custodian of the record. She has said this is the type of document maintained, but she has not said this record was. And so I don't think 803(6) is satisfied for that reason. 04:19:49

MR. LOPEZ: May I, Your Honor?

THE COURT: Yeah.

MR. LOPEZ: Here's the point. These were both produced by Bard.

MS. HELM: No. 04:19:58

MR. LOPEZ: Yes, they were. We got them both from you.

THE COURT: Quiet.

MR. LOPEZ: We didn't subpoena these.

THE COURT: Hey. Look. Stop talking to each other. 04:20:03

MR. LOPEZ: I'm sorry. These were produced to us by Bard, both of these documents. If you look at them, they look like they are the exact same document. 04:20:07

This was produced by the vendor apparently to Bard; right? 04:20:21

They produced it to us. It's the same document except for the fact Bard's copy says "evaluate." This one says "redesign."

THE COURT: But it's a different document.

MR. NORTH: Right. 04:20:33

THE COURT: Look at the rest of the page.

MR. LOPEZ: That's the point. The point is, whatever Bard produced as part of their records, this came from the vendor.

THE COURT: My problem, Mr. Lopez, is to get this document in, you need to have a witness who can testify that this document was maintained in the ordinary course of Bard's business. And there has been no testimony so far about that. She has looked at it and said, "I don't know if I've ever seen this. This type of document was maintained." 04:20:46 04:21:02

MR. LOPEZ: But she said the same thing about this one.

THE COURT: Well, that came in without an objection and there's an objection to this one and so you have to meet 803(6). 04:21:12

MR. LOPEZ: Your Honor, if this purports to be reporting about the same series of events -- 04:21:14

THE COURT: Mr. Lopez, I understand what you're saying about the document. I understand why you think it's relevant. But I can't let it in under 803(6) unless there is a witness who says Exhibit 704 satisfies the business record requirements. 04:21:24

MR. LOPEZ: This can't come in as an impeachment document, one of Bard's own documents?

THE COURT: It's hearsay. 04:21:38

MR. LOPEZ: Impeachment is an exception to the hearsay rule.

THE COURT: What are you referring to?

MR. LOPEZ: I'm referring to the fact this is --

THE COURT: Which rule are you referring to? 04:21:45

MR. LOPEZ: Well, whatever the impeachment rule is.

THE COURT: That doesn't help me. Hold on just a minute. I mean, are you --

MR. LOPEZ: This impeaches a Bard document.

THE COURT: But you have got to help me here, Mr. Lopez. 04:22:01

MR. LOPEZ: I'm trying.

THE COURT: Hold on.

MR. LOPEZ: An exception to the hearsay rule is impeachment. 04:22:09

THE COURT: Where? Cite it for me. Worst thing that could happen at 4:20 on a Friday evening is the jury waiting and my hearing in seven minutes. 04:22:10

I think what he's referring to is 804.

Mr. Lopez, come here for a minute. 04:22:39

Mr. Lopez, I think, based on -- you're saying impeachment is an exception, you're referring to 804 and you're referring to 804(b) I'm assuming? But this is when a witness is unavailable, when a declarant is unavailable. There's former testimony, there's a statement against interest. I don't know what else you're referring to as an exception. 04:23:00

MR. LOPEZ: This went to Bard. These are both from a medical --

THE COURT: I understand all of that. But you're not answering my problem, which is, there is no witness who has said that Exhibit 704 was maintained in the ordinary course of business so it hasn't been established under 803(6). That's my problem. 04:23:19

MR. LOPEZ: Well, this is a document that Bard maintains in the ordinary course. 04:23:35

THE COURT: There's no witness that has said that. You're saying it. She didn't say that. That's my problem.

MR. LOPEZ: But she did.

THE COURT: No, she didn't. She said this type of document was maintained but she said she's never seen this. 04:23:46

She didn't say this document was maintained. And that is what has to happen for 803(6) to apply. 04:23:49

Now, we did can't keep the jury waiting much longer. I want to hear from you again.

MR. LOPEZ: Okay. 04:24:00

THE COURT: I want to make sure I'm ruling on all of your arguments.

MR. LOPEZ: Do you have another one for me?

MR. NORTH: I have another argument, Your Honor. There's a serious 901 issue. We've never seen that document. 04:24:12 It's not in our files, the 704 one.

MR. LOPEZ: You gave it to us.

MR. NORTH: No, we didn't.

THE COURT: Guys, don't talk to each other. Don't talk to each other. 04:24:24

My ruling is that 803(6) has not been satisfied for Exhibit 704, and I have seen no other hearsay exception that has been identified that will allow it to be admitted over hearsay objection.

MR. LOPEZ: May I make one more statement? 04:24:37

THE COURT: You may.

MR. LOPEZ: Keep in mind that this litigation is an MDL litigation. The production of these documents came over the course of a lot of years. We've sent out -- these are specifically -- these are supposedly certified documents from 04:24:49

this company when they produced it. 04:24:53

He was relieved from having to produce 2 million documents because they got produced before. We sent out requests for admissions before.

THE COURT: Cut to the chase. I know all of that. 04:25:02 What is the point?

MR. LOPEZ: The point is, this is a bellwether case, Your Honor. All of these documents that we've gotten, if we have to start -- if we have to lay the kind of foundation you're talking about for all of the documents that have been 04:25:14 produced -- this is the first time this has come up in a trial -- for every document that was produced by Bard. I mean, we've got --

THE COURT: Well, Mr. Lopez, there is no MDL or bellwether exception to the hearsay rule. 04:25:27

MR. LOPEZ: I know, but shouldn't it be in the interest of the fact that these documents have been used in prior depositions? They have been used. They were produced by Bard. They are Bates stamped by Bard. They are Bard's documents that they maintain in the ordinary course of their 04:25:39 business. How do we find a witness for this?

THE COURT: Well, we can talk in a minute about how I think you could have done that without great difficulty but that's not the point. The point is, everything you have just said, although I understand it, is not an exception to the 04:25:53

hearsay rule so I'm going to sustain the objection. 04:25:55

(End sidebar at 4:26.)

THE COURT: Thank you very much for your patience, ladies and gentlemen. I'm going to sustain the objection to be Exhibit 704. 04:26:06

Do you have anything further, Mr. O'Connor?

MR. O'CONNOR: No more questions, Your Honor.

MR. NORTH: Nothing further.

THE COURT: Okay.

Thanks for your patience, ladies and gentlemen. 04:26:14

Remember, we're going to be in trial on Monday, unlike this week, so we'll plan to start at 9 o'clock on Monday morning. Please don't do any research or investigation or discuss the case over the weekend. And we'll see you on Monday morning. 04:26:31

Thanks.

(Jury departs at 4:26.)

THE COURT: Please be seated or leave if you want to leave. I want to give you the time and I want to talk to you about a couple of other matters. 04:27:05

I don't think we played any depositions today, did we?

MR. NORTH: The morning one but I don't believe --

THE COURT: Do we have some time to adjust?

MS. HELM: Your Honor, three minutes to the 04:27:18

defendant. 04:27:19

THE COURT: Okay. But does plaintiff counsel agree with that?

MS. MATARAZZO: Yes, Your Honor.

THE COURT: As of the end of today, plaintiff has used 25 hours and 48 minutes and defendants have used 11 hours and 34 minutes. 04:28:08

Let's talk about a couple of things -- well, I want to make sure that we're in agreement on what's happening this weekend. You all are going to be talking about these -- it sounds to me like 15 or 20 exhibits now where -- well, Traci has actually been writing them down, nine exhibits you're going to confer about whether there is material one side or the other thinks needs to be excluded. 04:28:25

I'm not sure how best to have you raise that with me or when; but if it's going to require some sort of argument and ruling from me, we've got to figure out a way to do that early next week. 04:28:52

MS. MATARAZZO: Your Honor, I think we'll probably be able to work it out because we worked pretty cooperatively together; but in the event we can't, we can probably resolve whatever remains at 8:30 on Monday morning. 04:29:09

THE COURT: All right. Why don't you let me know whatever it is and we'll probably take it up?

MS. HELM: Your Honor, just to make sure, would it be 04:29:25

okay if Traci read the nine numbers to us? 04:29:28

THE COURT: I can read them to you. 5169, 5239, 5354, 5189, 5349, 5325, 5003, 5350, 6064 and 6061. So let me know where we stand on Monday with that.

Secondly, I think you're still going to get me this short briefing on the FDA letter at some point over the weekend. 04:30:12

MR. NORTH: I think our latest discussions were, given your comments, 5 o'clock on Sunday?

THE COURT: Okay. That's fine. I'll probably not look at those until Monday at noon or Monday evening. 04:30:21

I still have four deposition designations from the defendants. Do you want me to rule on objections in those?

MS. HELM: Your Honor, we'll withdraw the designations of Brian Barry, B-A-R-R-Y. 04:30:39

THE COURT: Okay. I won't review Barry then.

And the last thing I wanted to mention is, we will get you maybe Monday morning but in any event sometime on Monday a red-line version of the jury instructions and I have moved my hearing at 4:30 on Tuesday so we'll plan after the trial day on Tuesday to talk about the jury instructions again and you'll have them before that what changes I made on the basis of our discussion last evening. 04:31:02

04:31:19

Are there other matters that we need to cover before we break? 04:31:19

MS. MATARAZZO: Not that I'm aware of Your Honor.

MR. NORTH: Nothing for the defendants Your Honor.

THE COURT: Okay. We'll see you on Monday. Thank you. 04:31:27

(Whereupon, these proceedings recessed at 4:31 p.m.)

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C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 24th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP